UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THOMAS P. DINAPOLI, COMPTROLLER OF THE STATE OF NEW YORK, AS ADMINISTRATIVE HEAD OF THE NEW YORK STATE AND LOCAL RETIREMENT SYSTEM, AND AS TRUSTEE OF THE NEW YORK STATE COMMON RETIREMENT FUND, derivatively on behalf of ABBOTT LABORATORIES,

Plaintiff,

v.

ROBERT B. FORD, ROBERT J. ALPERN, ROXANNE S. AUSTIN, CLAIRE BABINEAUX-FONTENOT, SALLY E. BLOUNT, PAOLA GONZALEZ, MICHELLE A. KUMBIER, EDWARD LIDDY, PHEBE N. NOVAKOVIC, DARREN W. MCDEW, NANCY MCKINSTRY, WILLIAM A. OSBORN, MICHAEL F. ROMAN, SAMUEL C. SCOTT III, DANIEL J. STARKS, JOHN G. STRATTON, GLENN F. TILTON, MILES D. WHITE, CHRISTOPHER J. CALAMARI, ROBERT E. FUNCK, JR., J. SCOTT HOUSE, JOSEPH MANNING, LORI J. RANDALL, and DANIEL SALVADORI

Defendants,

and

ABBOTT LABORATORIES,

Nominal Defendant.

Case No. 1:23-cv-04142

VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT

Plaintiff Thomas P. DiNapoli, Comptroller of the State of New York, as Administrative Head of the New York State and Local Retirement System, and as Trustee of the New York State Common Retirement Fund ("NYSCRF"), shareholder of Abbott Laboratories ("Abbott," the "Company," or "Nominal Defendant"), brings this shareholder derivative action on Abbott's behalf against the current and former officers and directors identified below (collectively, "Defendants") arising from their failure to monitor the conditions of production and safety of powdered infant formula at Abbott's Sturgis, Michigan facility (the "Sturgis Facility" or "Sturgis"). Plaintiff, through its counsel, has conducted an investigation into the facts supporting the allegations in this Complaint, including the review of publicly available information, filings by Abbott with the Securities and Exchange Commission ("SEC"), material obtained through multiple Michigan and federal public records requests, records of Congressional proceedings, documents obtained under 805 Illinois Compiled Statutes 5/7.75,[1] and additional investigation and input from subject-matter experts.

I. NATURE OF THE ACTION

1. On February 17, 2022, Abbott announced it would recall 70 million cans of powdered infant formula manufactured at its Sturgis Facility in Michigan (the "Abbott Formula Recall" or "Recall"). Two days earlier, in the midst of a for-cause Food and Drug Administration ("FDA") inspection, Abbott ceased all manufacturing at Sturgis (the "Sturgis Shutdown"). Abbott manufactures 40% of the infant formula sold in the United States, and the Sturgis Facility alone manufactured a quarter of all formula sold domestically.

[1] Abbott produced 185 documents totaling over 5,400 pages to Plaintiff. It is reasonable to infer that exculpatory information not reflected in the document production does not exist. *See Teamsters Local 443 Health Servs & Ins. Plan v. Chou*, C.A. No. 2019-0816-SG, 2020 WL 5028065, at *24, n.314 (Del. Ch. Aug. 24, 2020). "Illinois case law follows Delaware law in establishing demand futility requirements…" *In re Abbott Labs. Derivative S'holders Litig.*, 325 F.3d 795, 803 (7th Cir. 2003).

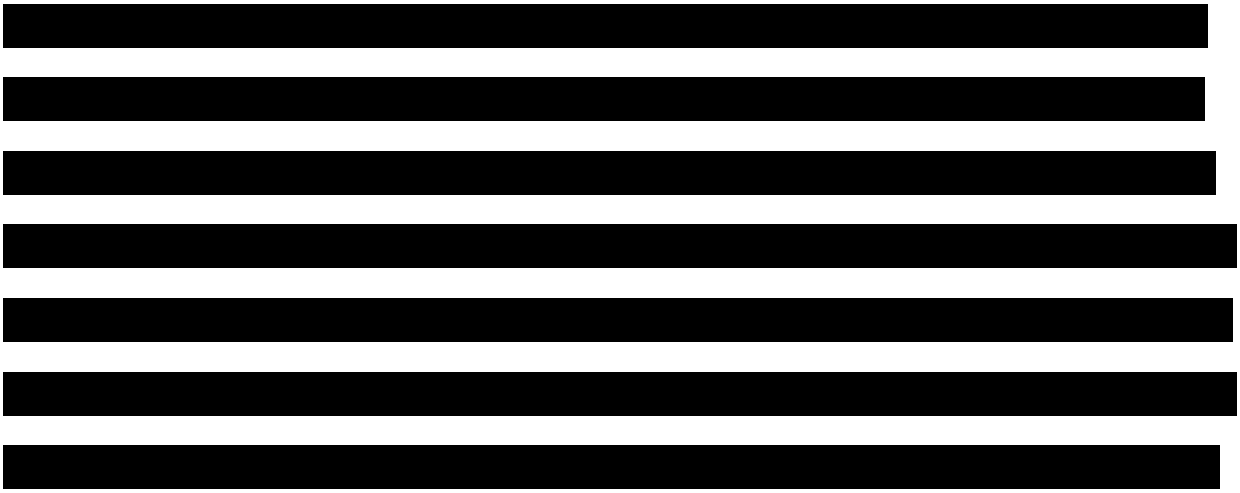
2. The FDA's for-cause inspection of Sturgis was precipitated by reports of several deaths of infants from cronobacter infection who consumed Abbott's powdered infant formula. Cronobacter causes meningitis, a swelling of the linings around the brain and spinal cord, and sepsis, a blood infection. It is particularly life threatening to infants, for whom it has a mortality rate of up to eighty percent. The FDA's inspection uncovered "egregiously unsanitary conditions" at Sturgis, including widespread cronobacter contamination.

3. Internal Abbott documents reveal that [redacted]

4. [redacted]

However, it resulted directly from repeated pressure in the preceding days from the FDA to issue a recall and coincided with the FDA's issuance of a consumer advisory warning that "consumers not [] use Similac, Alimentum, or EleCare powdered infant formula" from the Sturgis Facility because the FDA "[wa]s investigating consumer complaints of *Cronobacter sakazakii* and *Salmonella* Newport" infections linked to Sturgis. Indeed, production at Sturgis had already stopped by the time the Abbott Formula Recall was announced.

5. Defendants had not established a system of reporting that ensured the Board was regularly briefed on mission-critical risks to the Company's business, such as the safety of its infant formula. Thus, prior to the date of the Recall announcement, Abbott's Board was completely unaware that there were severe sanitation issues at the Sturgis Facility that ultimately made the Company's powdered infant formula product unsafe. [redacted]



6. Abbott management, including the Officer Defendants in this action, had long been aware that the conditions at Sturgis were deteriorating in the years leading up to the Abbott Formula Recall and the Sturgis Shutdown, putting the safety of the Facility's product at risk. Beginning in 2019, *three years before the Abbott Formula Recall was announced*, yearly FDA inspections uncovered significant safety and cleanliness violations at the Sturgis Facility which Abbott consistently failed to correct. The inspections flagged conditions that created a ripe environment for bacteria growth, including standing water and moldy equipment. During the same time period, Abbott's internal product testing revealed that finished product formula was contaminated with potentially deadly bacteria, including cronobacter. Abbott had received reports from parents, doctors, and nurses that infants who consumed formula manufactured at Sturgis had become ill with cronobacter and other infections. A former quality assurance employee at Sturgis (the "Sturgis Whistleblower") submitted a comprehensive whistleblower complaint (to the federal Occupational Safety and Health Administration ("OSHA"), and then to the FDA) detailing serious misconduct at the Sturgis Facility, including Sturgis management's efforts to mislead the FDA so that the regulatory agency would not discover the extent of the unsanitary conditions at

the Facility. Abbott's Officers dismissed the Sturgis Whistleblower's claims out of hand, even though they were corroborated by regulatory inspections by the FDA.

7. Directors owe fiduciary duties to the company on whose board they serve. Among those duties is a duty of oversight, which requires directors and officers to make a good faith effort to implement proper reporting systems, and to address "red flags" of corporate wrongdoing. Corporate officers have the same fiduciary duties as directors. Abbott's directors and officers failed on both counts. The Board did not establish a system of reporting that ensured it received critical information about mounting safety and cleanliness issues at its primary infant formula manufacturing plant, and thus was unable to effectively oversee Abbott management's response to the risks to the infant formula business. Meanwhile, Abbott's officers were consciously disregarding red flags concerning the manufacturing conditions at Sturgis, which called into question whether the product was safe for consumption by infants. Consequently, when Abbott officers were finally forced to shut down Sturgis, and the Board finally did hear of the Abbott Formula Recall, Directors were wholly unable to respond because they lacked any meaningful, real-time information about the ongoing safety failures at Sturgis. Instead, the Board continued deferring to the Abbott management team that had fostered the Company's perilous risk in the first instance.

8. Abbott's Board's passivity is especially egregious since it was well-aware of the importance of implementing effective board-level reporting systems. Many of the Directors had been defendants in earlier shareholder derivative actions against Abbott's Board claiming it had not overseen risks to the Company's business, and settlement of those suits had included guidance on establishing board-level reporting mechanisms. The system the Board ultimately established, and which governed its response to the Abbott Formula Recall and Sturgis Shutdown, was

inadequate. As described herein, [redacted]

9. Abbott's Board's Public Policy Committee, which is the only Committee purportedly tasked with assisting the Board in oversight of regulatory and compliance issues, does not—either by charter or in practice—actually oversee product safety. [redacted]

10. The Board consciously disregarded the red flags of the Abbott Formula Recall and Sturgis Shutdown, which revealed Abbott's management's bad faith failure to ensure the cleanliness of the Sturgis Facility and, by extension, the safety of its infant formula product. [redacted]

11. Following the announcement of the Abbott Formula Recall, Abbott was forced to grapple with an onslaught of regulatory scrutiny. The Abbott Formula Recall put the Board on notice that Abbott management, including the Officer Defendants, had not appropriately responded to regulatory, compliance, and safety issues in the infant formula business unit, and the resulting harm to the Company. Nevertheless, the Directors maintained their existing model of complete deference to management. Specifically, as the fall-out continued, [redacted]

12. Shortly thereafter, still absent any Board involvement or oversight, Abbott expanded the Abbott Formula Recall. Specifically, just eleven days after the Recall was first announced, and following a report that yet another infant had died of cronobacter after consuming Abbott's powdered infant formula, the Company was forced to recall additional product. [redacted]

13. On March 18, 2022, the FDA completed its for-cause inspection and concluded that powdered infant formula from the Sturgis Facility was "produced under unsanitary conditions and may be contaminated with Cronobacter." Even though the Facility remained closed, the Directors passively deferred to Abbott management to handle the response to the FDA (which Abbott submitted on April 8, 2022). [redacted]

14. The United States Department of Justice (the "DoJ") consequently investigated Abbott's Sturgis Facility. That investigation resulted in a civil consent decree (the "Consent Decree") filed May 16, 2022 against Abbott and three Sturgis managers that required the Company to take remedial steps before it could resume manufacturing at the Sturgis Facility in order to ensure the safety of Abbott's powdered infant formula.[2] [redacted]

15. The complaint submitted by the Sturgis Whistleblower to the FDA, the substance of which Abbott management had known about for at least a year, was made public by a member of Congress on April 28, 2022. Despite widespread public reporting on the Sturgis Whistleblower complaint following that disclosure, [redacted]

[2] Press Release, Dep't of Just., *Justice Department Files Complaint and Proposed Consent Decree to Ensure Safety of Abbott Laboratories' Infant Formula* (May 16, 2022), https://www.justice.gov/opa/pr/justice-department-files-complaint-and-proposed-consent-decree-ensure-safety-abbott.

[redacted] By that point, both houses of Congress had opened investigations and demanded that Abbott produce documents about the Abbott Formula Recall and Sturgis Shutdown, and Abbott's representative—Calamari—had already testified before Congress. Yet again, the Abbott Board's lack of effective reporting system meant it learned information as and when management determined to share it, rather than as a matter of course.

16. Abbott's Board of Directors and those Officers overseeing the infant formula division breached their fiduciary duty of oversight. The Officers were consistently made aware of mission-critical risks to the safety of the Company's formula product arising from sanitation problems at Sturgis, but failed to act. At the same time, the Board had failed to establish a system of board-level reporting that would ensure Directors had sufficient background and context with which to evaluate Abbott management's handling of Sturgis. The Directors remained uninformed and inactive even after they were put on notice of the risk to the Company's business from the Abbott Formula Recall. Abbott's Directors also violated Section 14(a) of the Exchange Act, and breached their fiduciary duties, when they emphasized to shareholders the Company's purported strong corporate governance as a reason for shareholders to support their reelection, award compensation, and reject a shareholder proposal for an independent chairperson, which was included in proxy statements filed with the Securities and Exchange Commission.

17. The Abbott Formula Recall and Sturgis Shutdown has caused Abbott damages of hundreds of millions of dollars. For example, in its August 2022 Quarterly Report filed with the SEC, Abbott stated that sales of "infant powder formulas associated with the recall" were $393 million less in the first six months of 2022 than the first six months of 2021.[3] The Company also lost market share in the powdered infant formula market, and the safety of its products for

[3] Abbott, Quarterly Report (Form 10-Q) (Aug. 2, 2022), at 24.

consumption by infants has been called into question. Further, Abbott's SEC filings also revealed that the Company learned in November 2022 that the DoJ was conducting a criminal investigation "related to Abbott's manufacturing of infant formula."

18. Plaintiff brings this shareholder lawsuit to recoup the damage to Abbott resulting from the breaches of fiduciary duties by the Company's Directors and Officers and the associated proxy solicitations.

II. PARTIES

A. Plaintiff

19. Thomas P. DiNapoli is Comptroller of the State of New York, Administrative Head of the New York State and Local Retirement System, and Trustee of the New York State Common Retirement Fund ("NYSCRF"). NYSCRF is a public pension fund for the employees of New York State and local governments. As of December 31, 2022, its fund value was $242.3 billion. NYSCRF has been a continuous holder of Abbott shares at all relevant times. As of March 31, 2023, NYSCRF held approximately 3,017,901 shares of Abbott worth more than $300 million.

20. NYSCRF supports sound environmental, social and corporate governance practices which generate long-term value for investors. Its Corporate Governance Program pursues NYSCRF's goals through direct engagement with the companies in which it invests, shareholder proposals, proxy votes, and shareholder lawsuits, including derivative actions.

21. In 2020, for example, *In re The Boeing Company Derivative Litigation*, No. 2019-0907-AGB (Del. Ch.) (the "*Boeing* Action"), NYSCRF sued Boeing's officers and directors for failing to monitor the safety of Boeing's aircraft following two fatal crashes of Boeing's 737 MAX planes. The *Boeing* Action resulted in historic monetary relief of $237.5 million and extensive corporate governance reforms including requiring Boeing to elect a new director

specifically with "knowledge, experience, and/or expertise in aviation/aerospace, engineering, and/or product safety oversight," amend its Corporate Governance Principles to ensure that at least three directors have "knowledge, experience, and/or expertise with aviation/aerospace, engineering, and/or product safety oversight," and establish an Ombudsperson Program to create an "additional channel" to escalate and remedy the product safety issues addressed by the *Boeing* Action.

B. Nominal Defendant

22. Nominal Defendant Abbott is an Illinois corporation. Describing itself as "mak[ing] the world a better place by bringing life-changing health technologies to the people who need them," Abbott is one of the largest manufacturers of infant formula in the United States. Its principal executive headquarters is at 100 Abbott Park Road, Abbott Park, Illinois 60064. The Company operates in seventy-seven countries. In 2022, the Company reported $43.7 billion in revenue.

C. Defendants

1. Director Defendants

23. Defendant Robert B. Ford ("Ford") is Abbott's Chairman of the Board ("Chairman") and Chief Executive Officer ("CEO"). Ford became Abbott's CEO and President in March 2020 and its Chairman in 2021. Prior to that appointment, Ford was Abbott's President and Chief Operating Officer ("COO") from 2018 to 2020, and previously the Company's Executive Vice President of Medical Devices. Ford has been a director of Abbott since 2019 and is currently the chair of its Executive Committee. From the beginning of his tenure as CEO through 2022, Ford received over $78.9 million in compensation for serving as Abbott's CEO. Ford resides in Illinois.

24. Defendant Robert J. Alpern, M.D ("Alpern") has been a director of Abbott since 2008. Alpern serves on the Board's Nominations and Governance Committee, and its Public Policy Committee. Alpern is the Ensign Professor of Medicine and Physiology and Professor of Internal Medicine and Cellular and Molecular Physiology at Yale School of Medicine. Alpern also serves on the boards of the pharmaceutical companies AbbVie Inc. ("AbbVie") and Tricida, Inc. From 2019 to 2022, Alpern received over $1.5 million in compensation for serving as an Abbott director. Alpern resides in Connecticut.

25. Defendant Roxanne S. Austin ("Austin") was a director of Abbott from 2000 to April 2022. Austin served on four Board committees: as the Chair of the Compensation Committee, and on its Audit Committee, Nominations and Governance Committee, and Executive Committee. Austin is the President and CEO of Austin Investment Advisors, a private investment and consulting firm. Austin currently serves on AbbVie's board with Alpern. From 2019 to 2022, Austin received over $1.1 million in compensation for serving as an Abbott director. Austin resides in California.

26. Defendant Claire Babineaux-Fontenot ("Babineaux-Fontenot") has been a director of Abbott since September 2022. Babineaux-Fontenot serves on the Board's Public Policy Committee and its Audit Committee. Since 2018, Babineaux-Fontenot has been CEO of Feeding America, a charity working to end hunger in the United States. As a Board member since September 2022, Babineaux-Fontenot has received over $31,000 in compensation for serving as an Abbott director. Babineaux-Fontenot resides in Texas.

27. Defendant Sally E. Blount, Ph.D. ("Blount") has been a director of Abbott since 2011. Blount serves on the Board's Nominations and Governance Committee, and its Public Policy Committee. Since August 2020, Blount has been the President and CEO of Catholic

Charities of the Archdiocese of Chicago. Blount served on the Board of Ulta Beauty, Inc. From 2019 to 2022, Blount received over $1.3 million in compensation for serving as an Abbott director. Blount resides in Illinois.

28. Defendant Paola Gonzalez ("Gonzalez") has been a director of Abbott since April 2021. Gonzalez serves on the Board's Audit Committee and its Nominations and Governance Committee. Since January 2018, Gonzalez has been the Vice President and Treasurer of The Clorox Company. From 2019 to 2022, Gonzalez received over $360,000 in compensation for serving as an Abbott director. Gonzalez resides in California.

29. Defendant Michelle A. Kumbier ("Kumbier") has been a director of Abbott since 2018. Kumbier serves on the Board's Audit Committee and its Compensation Committee. Kumbier is the President of Turf & Consumer Products at Briggs & Stratton, LLC, an engine manufacturer. From 2019 to 2022, Kumbier received over $1.2 million in compensation for serving as an Abbott director. Kumbier resides in Wisconsin.

30. Defendant Edward Liddy ("Liddy") was a director of Abbott from 2010 to April 2020. Liddy served on the Board's Audit Committee (of which he was the Chair in 2019 and 2020), its Compensation Committee, and its Executive Committee. Most recently, Liddy was a partner at private equity firm Clayton, Dubilier & Rice, LLC from 2010 to 2015. Liddy also previously served on the AbbVie board and the board of directors of 3M Company and the Boeing Company (and, in that capacity, was a defendant in the *Boeing* Action, referenced *supra*). From 2019 to 2020, Liddy received over $700,000 in compensation for serving as an Abbott director. Liddy resides in Illinois.

31. Defendant Phebe N. Novakovic ("Novakovic") was a director of Abbott from 2010 to April 2021. Novakovic served on three Board committees: the Public Policy Committee (of

which she was the Chair in 2019 and 2020), the Compensation Committee, and the Executive Committee. Since 2013, Novakovic has been Chairman of the Board and CEO of General Dynamics. Novakovic also serves as a director of J.P. Morgan Chase. From 2019 to 2021, Novakovic received over $680,000 in compensation for serving as an Abbott director. Novakovic resides in Virginia.

32. Defendant General Darren W. McDew ("McDew") has been a director of Abbott since September 2019. McDew serves on the Board's Nominations and Governance Committee, and its Public Policy Committee. McDew is a retired general of the United States Air Force. McDew also serves on the Board of General Electric and Parsons Corporation. From 2019 to 2022, McDew received over $960,000 in compensation for serving as an Abbott director. McDew resides in North Carolina.

33. Defendant Nancy McKinstry ("McKinstry") has been a director of Abbott since 2011. McKinstry serves on the Board's Audit Committee (of which she had been the Chair since 2021), its Compensation Committee and its Executive Committee. Since September 2003, McKinstry has been the CEO and Chairman of the Executive Board of Wolters Kluwer N.V. McKinstry also serves on the boards of Accenture PLC and the Board of Overseers of Columbia Business School. From 2019 to 2022, McKinstry received over $1.3 million in compensation for serving as an Abbott director. McKinstry resides in the Netherlands.

34. Defendant William A. Osborn ("Osborn") was a director of Abbott from 2008 until April 2023. Osborn was the Company's Lead Independent Director. Osborn served on the Board's Compensation Committee, its Nominating and Governance Committee (of which he was the Chair from April 2013 to April 2023) and its Executive Committee. Osborn was the Chairman and CEO of Northern Trust Corporation from 1995 to 2009. Osborn served on the boards of the

Tribune Company, Caterpillar Inc., and General Dynamics Corporation. From 2019 to 2022, Osborn received over $1.3 million in compensation for serving as an Abbott director. Osborn resides in Illinois.

35. Defendant Michael F. Roman ("Roman") has been a director of Abbott since April 2021. Roman serves on the Board's Audit Committee, its Compensation Committee, and its Public Policy Committee (of which he has been the Chair since April 2023). Roman is the Chairman of the Board, President, and CEO of the 3M Company. From 2021 to 2022, Roman received over $580,000 in compensation for serving as an Abbott director. Roman resides in Minnesota.

36. Defendant Samuel C. Scott, III ("Scott") was a director of Abbott from 2007 to April 2020. Scott served on the Board's Audit Committee and its Compensation Committee. Scott was the Chairman, President, and CEO of Corn Products International, Inc. Scott served on the boards of Northwestern Medical Group, Motorola Solutions, Inc., and the Bank of New York Mellon Corporation. From 2019 to 2020, Scott received over $375,000 in compensation for serving as an Abbott director. Scott resides in Illinois.

37. Defendant Daniel J. Starks ("Starks") has been a director of Abbott since 2017. Starks serves on the Board's Public Policy Committee and its Executive Committee and has been Chair of the Compensation Committee since April 2023. Starks was the Chairman, President, and CEO of St. Jude Medical, Inc. from 2001 until Abbott acquired the company in 2017. From 2019 to 2022, Starks received over $1.2 million in compensation for serving as an Abbott director. Starks resides in Minnesota.

38. Defendant John G. Stratton ("Stratton") has been a director of Abbott since 2017. Stratton serves on the Board's Audit Committee, its Executive Committee, and since April 2023,

is the Chair of the Nominations and Governance Committee. Between 2018 and April 2023, Stratton served on the Board's Public Policy Committee. Stratton is the Executive Chairman of telecoms company Frontier. From 2019 to 2022, Stratton received over $1.2 million in compensation for serving as an Abbott director. Stratton resides in Connecticut.

39. Defendant Glenn F. Tilton ("Tilton") has been a director of Abbott from 2007 to April 2023. Tilton served on the Board's Audit Committee, its Public Policy Committee (of which he was its Chair from 2021 to April 2023), and its Executive Committee. Tilton previously was the Chairman and CEO of United Air Lines. Tilton serves on the boards of AbbVie and petroleum company Phillips 66. From 2019 to 2022, Tilton received over $1.3 million in compensation for serving as an Abbott director. Tilton resides in Illinois.

40. Defendant Miles D. White ("White") was a director of Abbott from 1998 to December 2021. White served as Chair of the Executive Committee in 2020. White joined Abbott in 1984 and was elected CEO and Chairman in 1999, positions he held until 2020. White serves on the board of McDonalds Corporation and previously served on the board of Caterpillar, Inc. White was a chairman of the Federal Reserve Bank of Chicago and the Pharmaceutical Research and Manufacturers of America. From 2019 to 2021, White received over $63.5 million in compensation for serving as Abbott's CEO. White resides in Illinois.

41. Ford, Alpern, Austin, Babineux-Fontenot, Blount, Gonzalez, Kumbier, Liddy, McDew, McKinstry, Novakovic, Osborn, Roman, Scott, Sparks, Stratton, Tilton, and White are referenced collectively in this Complaint as the "Director Defendants."

2. Officer Defendants

42. Defendant Christopher J. Calamari ("Calamari") has been Abbott's Senior Vice President, U.S. Nutrition since July 2021. In that role, he "lead[s] Abbott's U.S. nutrition business, which includes [the Company's] portfolio of infant formula products." Prior to that,

Calamari served as Vice President, Pediatric Nutrition, and held various marketing positions in the Nutrition and Pharmaceuticals business. Calamari joined Abbott in 2005. Calamari resides in Illinois.

43. Defendant Robert E. Funck, Jr. ("Funck") has been Abbott's Executive Vice President, Finance and Chief Financial Officer since March 2020. Prior to that, Funck was a Senior Vice President, and Controller. From 2019 to 2022, Funck received over $28 million in compensation for serving as Abbott's CFO. Funck resides in Illinois.

44. Defendant J. Scott House ("House") has been Abbott's Senior Vice President, Quality Assurance, Regulatory and Engineering Services since March 2020. House joined Abbott in 1990. According to House's biography on Abbott's website, House and his team are responsible for "ensuring that Abbott's quality, regulatory and engineering values are consistently applied across the corporation, helping ensure the highest quality products for our customers, strict compliance with global regulatory requirements, and a safe environment. . . ." House resides in Illinois.

45. Defendant Joseph Manning ("Manning") has served as Abbott's Executive Vice President, Nutritional Products since December 2021, "defining the strategic vision for [Abbott's] global nutrition business and leading Abbott's efforts to create science-based nutritional products for people of all ages." Manning joined Abbott in 1995 and has held various positions within Abbott's Pharmaceutical and Nutrition organizations worldwide. Manning resides in Illinois.

46. Defendant Lori J. Randall ("Randall") is Abbott Nutrition's Division Vice-President of Quality Assurance. Randall joined Abbott in 1993. Randall has overall responsibility for quality operations for global Abbott Nutrition which includes, but is not limited to, oversight of manufacturing locations and food safety, product quality, supplier quality, compliance,

complaint management, and corrective and preventive actions.[4] In a December 2021 interview with Quality Assurance & Food Safety Magazine, Randall claimed "that food safety and quality are everyone's responsibilities," and that at "Abbott, we protect our product through the actions and the behaviors. It's very easy to put the customer first and see that face of the customer when you're thinking about food safety." Five months later, the DoJ's civil complaint, filed alongside the proposed Consent Decree, identified "[o]ngoing inadequacies in manufacturing conditions and practices at Defendants' facilities demonstrate that [Abbott, Keenan Gale, TJ Hathaway, and Lori Randall] have been unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants."[5] Randall resides in Michigan.

47. Defendant Daniel Salvadori ("Salvadori") has served as Abbott's Executive Vice President and Group President, Established Pharmaceuticals and Nutritional Products since December 2021. In that role he is "responsible for defining the strategic vision for both of these businesses and leading efforts to create innovation-led and science-based products and medicines for people of all ages." Previously, Salvadori served as Abbott's Executive Vice President, Nutritional Products, and as Senior Vice President, Established Pharmaceuticals, Latin America. Salvadori resides in Illinois.

48. Ford, Calamari, Funck, House, Manning, Randall and Salvadori are collectively referenced in this Complaint as the "Officer Defendants," and together with the Director Defendants, the "Defendants."

[4] *See* Complaint at ¶ 7, *United States v. Abbott Labs.*, No. 22-cv-00441 (W.D. Mich. May 16, 2022), ECF No. 1 ("DoJ Complaint").
[5] *See* DoJ Complaint, at ¶ 5.

III. JURISDICTION AND VENUE

49. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is complete diversity among the parties and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

50. This Court also has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1337, as well as Section 27 of the Securities Exchange Act of 1934 (the "Exchange Act") over the claims asserted herein for, *inter alia*, violations of Section 14(a) of the Exchange Act, 15 U.S.C. § 78n.

51. This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367(a).

52. This Court has jurisdiction over each of the Defendants because each Defendant either resides in Illinois or otherwise has sufficient minimum contacts with Illinois (or, in the case of Plaintiff's Exchange Act claim, with the United States as a whole) to render the exercise of jurisdiction by this Court permissible.

53. Venue is proper in this District under 28 U.S.C. § 1391(b) because Abbott conducts business and maintains its principal executive offices in this District and one or more of the Defendants resides in this District. Further, Abbott engages in numerous activities and conducts business here, which had an effect in this District.

IV. FACTUAL BACKGROUND

A. Abbott's Corporate History and Products.

1. Abbott's Board Structure.

54. Founded in 1888, and headquartered in Abbott Park, Illinois, Abbott is a health care company that manufactures and sells nutritional products, medical devices and diagnostics, and pharmaceutical drugs.

55. In 2013, Abbott separated its research-based pharmaceuticals business into the independent biopharmaceutical company AbbVie. In 2017, its largest acquisition to date, Abbott acquired St. Jude Medical, Inc., a leader in the medical device space, for $25 billion. Also in 2017, Abbott acquired diagnostics company Alere, Inc. for $5 billion. In 2023, Abbott announced plans to acquire Cardiovascular Systems for $890 million, a 50% premium over the company's share price before the deal was announced.

56. Abbott is overseen by a Board of Directors and its five standing committees: Audit; Compensation; Executive; Nominations and Governance; and Public Policy.

57. The Audit Committee is responsible for, among other things, overseeing Abbott's enterprise risk management.[6] In practice, [redacted] From 2019 to 2022, the Audit Committee consisted of Defendants Austin, Gonzalez, Kumbier, Liddy, McKinstry, Roman, Scott, Stratton, and Tilton.

58. Pursuant to its charter, the Public Policy Committee is responsible for, among other things, assisting the Board with overseeing public policy, and regulatory and compliance issues, including FDA regulation.[7] [redacted] From 2019 to 2022, the

[6] ABBOTT, AUDIT COMMITTEE CHARTER, https://dam.abbott.com/en-us/documents/pdfs/investors/audit-committee-charter.pdf.
[7] ABBOTT, PUBLIC POLICY COMMITTEE CHARTER, https://dam.abbott.com/en-us/documents/pdfs/investors/Public-Policy-Committee-Charter.pdf.

Public Policy Committee consisted of Defendants Alpern, Babineaux-Fontenot, Blount, McDew, Novakovic, Starks, Stratton, and Tilton. Defendants Stratton and Tilton sit on both the Audit and Public Policy Committees.

59. The Compensation Committee reviews, evaluates, and approves compensation of Abbott's officers who are Executive, Group, or Senior Vice Presidents.[8] The Nominations and Governance Committee identifies and recommends individuals to become Board members and officers of the Company.[9] And, finally, the Executive Committee, meeting on *ad hoc* basis, "may exercise all the authority of the board in the management of Abbott, except for matters expressly reserved by law for board action."[10]

2. The Abbott Board's History of Failing To Oversee the Company's Operations.

60. The Abbott Board has a history of failing to oversee the Company's business. Abbott's Board has settled two derivative actions in the last twenty years for alleged breaches of fiduciary duty.

a. *In re Abbott Laboratories*, No. 1:99-cv-07246: Abbott's Board Failed to Address Deficient Manufacturing Processes.

61. Like the instant suit, the first derivative settlement followed years of Abbott's Board failing to address repeated FDA censure, this time relating to Abbott's failure to correct deficiencies in its manufacture of medical diagnostic test kits. On November 2, 1999, after failing to correct *six years* of repeated compliance deficiencies despite repeated FDA warnings, Abbott agreed to a consent decree with the FDA that required it to pay a $100 million civil fine to the

[8] ABBOTT, COMPENSATION COMMITTEE CHARTER, https://dam.abbott.com/en-us/documents/pdfs/investors/compensation-committee-charter.pdf.
[9] ABBOTT, NOMINATIONS AND GOVERNANCE COMMITTEE CHARTER, https://dam.abbott.com/en-us/documents/pdfs/investors/nominations-governance-charter.pdf.
[10] Board of Directors & Committees, ABBOTT, https://www.abbott.com/investors/governance/board-of-directors-and-committees.html.

FDA, withdraw 125 types of medical diagnostic test kits from the market, destroy inventory, and cease manufacturing almost 300 medical-testing devices at Abbott facilities until the Company brought the facilities into compliance with FDA regulations.

62. Three days later, on November 5, 1999, several plaintiffs filed a shareholder derivative complaint in this district in an action that would become *In re Abbott Laboratories*, No. 1:99-cv-07246.[11] Building on the 1999 consent decree, the complaint alleged that Abbott's directors failed "to require management to bring Abbott into compliance with federal requirements." It further alleged that Abbott failed to address six years of compliance deficiencies identified by the FDA in its manufacturing of defective in vitro diagnostic kits used to diagnose a range of medical conditions from HIV to pregnancy. It alleged that cost-cutting measures reduced the quality of the kits and the Board was made aware of four formal Warning Letters from the FDA concerning quality assurance failures at the Company's diagnostic kit facilities over a six-year period. White, who was on the Board at the time, himself received the fourth and final Warning Letter from the FDA. Less than one month after receiving the fourth Warning Letter, White sold thirty percent of his Abbott stock for a total of $4.7 million. Plaintiffs argued that the Form 483s that the FDA sent were "clearly information that was required to be brought to the attention of the Board members by the Chairman . . . who had a duty to [do so]."

63. In March 2003, the Seventh Circuit reversed the district court, holding that plaintiffs sufficiently pled a breach of the duty of good faith to find that the directors' actions fell outside of the business judgment rule. The Seventh Circuit pointed to the fact that the Chairman of the Board received two FDA Warning Letters, White received a third, the members of the Audit Committee were aware of the violations, the FDA met at least ten times including with

[11] The complaints and motion to dismiss briefing in this case are sealed.

Defendants and other senior officers about the continuing violations, and that not even public exposure of Abbott's FDA issues by the *Wall Street Journal* "motivated the directors to take any action concerning the problems over a six-year period."

64. In 2004, Abbott's directors settled the derivative litigation for $27 million in funding for unspecified "regulatory/compliance activities" and adopted a version of the Public Policy Committee charter.

b. *In re Abbott-Depakote Shareholder Derivative Litigation*, No. 1:11-cv-08114: Abbott Failed to Address Improper Marketing and Promotional Red Flags.

65. Most recently, in 2012, Abbott pled guilty and agreed to pay $1.5 billion for unlawfully promoting its prescription drug Depakote for off-label uses to elderly dementia patients in nursing homes. The $1.5 billion payment consisted of a $500 million criminal fine, forfeiting $198.5 million in assets, and $800 million paid to the federal government and certain states. As part of the global resolution of criminal and civil proceedings, Abbott admitted that, for nearly ten years, the Company maintained a specialized sales force that marketed Depakote in nursing homes as a drug to control agitation and aggression in elderly dementia patients despite a lack of evidence that the drug was safe for those uses. From 1998 to 2008, Abbott made $13.8 billion in gross sales of Depakote.

66. As part of the criminal settlement, Abbott was subject to a five-year probation period and reporting obligations for the CEO and Board to the Department of Health and Human Services Office of Inspector General ("Office of Inspector General"). Abbott had to report any probable Food and Drug Cosmetic Act ("FDCA") violations to the probation office, its CEO had to certify compliance with this reporting requirement, and the Board was required to report annually to the Office of Inspector General on the effectiveness of the Company's compliance program. Funck, who was Abbott's V.P., Chief Ethics and Corporate Compliance officer at the

time, signed the probation agreement. As members of the Board at the time, Defendants Alpern, Austin, Blount, Liddy, McKinstry, Novakovic, Osborn, Scott, Tilton, and White approved the probation agreement and were directly responsible for ensuring its compliance.

67. On November 14, 2011, Abbott's directors were sued derivatively for allegedly breaching their fiduciary duties by failing to act while the Company carried out a fourteen-year scheme to market and sell Depakote for off-label uses that resulted in serious corporate trauma.

68. On January 31, 2013, plaintiffs filed an amended complaint alleging red flags that the Board failed to respond to: (1) a DoJ letter to Abbott's legal department stating it was investigating the marketing and promotion of Depakote; (2) DoJ subpoenas about Depakote that directed Abbott to collect information from employees including all past and present directors; (3) regular reports to the Board from the Pharmaceutical Products Division specifically addressing promotional and marketing strategies for Depakote; (4) an FDA letter to Abbott's regulatory manager requesting the Company stop using particular Depakote sales materials because they were misleading; and (5) presentations by the Office of Ethics Compliance to the Board detailing trends and risk areas in the pharmaceutical industry. On June 5, 2013, Judge Kendall denied defendants' motion to dismiss finding that the Board faced a substantial threat of personal liability. Judge Kendall also found that plaintiffs sufficiently alleged that a majority of the Board had knowledge of the wrongful conduct, and that "red flags" supported the reasonable inference that a majority of the Board had notice of the scheme, where the red flags were the DoJ preservation letter and the subpoenas that followed.

69. On March 6, 2014, Abbott agreed to settle the Depakote derivative case for corporate governance reforms that focused on strengthening the Board's oversight of compliance with federal healthcare programs and regulations. The settlement specifically mandated that the

Public Policy Committee undertake specific changes meant to help directors fulfill their oversight responsibility regarding regulatory and healthcare compliance issues. The Public Policy Committee was required to (1) meet at least four times a year; (2) annually review Abbott's legal and regulatory compliance program (including FDA regulation); (3) review such matters with the Board where appropriate; (4) receive at least three reports per year from the Chief Ethics and Compliance Officer regarding regulatory and healthcare compliance; and (5) receive at least two reports a year from the Head of Quality including on any FDA Warning Letters issued to the Company and the Company's response. As described herein, [redacted]

70. As a result of these previous regulatory fines and settlements, the Board was aware that its board-level safety and compliance reporting were inadequate. At least ten Defendants were members of the Board or Abbott executives at the time of the 2012 criminal settlement. Nevertheless, as described herein, the Directors failed to establish a reasonable board-level system of reporting about the safety of the Company's infant formula products, exposing the Company to significant liability and Abbott customers to overwhelming harm.

3. Abbott's Infant Formula Products.

71. Infant formula simulates human breastmilk and can be a complete or partial substitute for breastmilk for infants up to twelve months old. The American Academy of Pediatrics recommends that, at six months old, infants who have been consuming only breastmilk should start ingesting complementary foods, including infant formula. But breastfeeding rates drop sharply as mothers return to work, particularly for low-income mothers or racial or ethnic minority mothers who do not have access to paid family leave or work environments that allow

breaks to pump breastmilk and have refrigerated storage facilities for the milk. By six months, more than half of all infants who were breastfeeding will have switched to a partial or complete formula diet. Every year, more than a million American infants consume infant formula as part of, or as their entire, diet.

72. Infant formula is produced in two forms: powdered and ready-to-feed. Powdered infant formula must be mixed with water to create a liquid to feed the infant. Ready-to-feed formula is a pre-mixed liquid formula that is often used in hospitals because it is sterile. Powdered formula makes up approximately ninety-two percent of infant formula produced and sold in the United States, in large part because it is less expensive than ready-to-feed formula.

73. The infant formula market includes brands manufactured for healthy full-term infants, such as Abbott's Similac brand, as well as specialty formulas manufactured for infants with a range of medical conditions, such as Abbott's Alimentum and EleCare brands. Approximately six percent of infants fed formula consume specialty formula. Specialty formulas include hypoallergenic amino acid formulas for infants with allergies, and specialty metabolic formulas for infants with rare metabolic disorders that affect how infants process nutrients.

74. Abbott entered the infant formula market in 1964 when it purchased Ross Laboratories, which had been manufacturing Similac, the most popular infant formula brand in the country, since 1927. By the late 1940s, Similac was so popular that Ross established a second manufacturing facility, in Sturgis, Michigan. Abbott is currently the largest manufacturer of infant formula in the United States, holding approximately 40% of the market share (the majority of which is powdered formula). Before the Abbott Formula Recall and Sturgis Shutdown, Abbott produced approximately 25% of the powdered infant formula in the United States at Sturgis. In

particular, the facility manufactured 40% of Abbott's total production of Similac, the most popular infant formula brand on the market.

75. Abbott is also a significant supplier of specialty formulas for infants with medical conditions. Abbott manufactured most of its specialty formulas at the Sturgis Facility. Manufacturing these specialty formulas requires additional care for several reasons. First, metabolic and amino acid-based formulas are particularly complex to manufacture, and cannot be easily manufactured at other facilities. Second, infants who rely on specialty formulas cannot easily change to alternatives. In some cases, during the formula shortage that followed the Sturgis Shutdown, parents had to take their infants to the hospital to be fed intravenously because they could not find the specialty formula their infant needed. Third, infants with medical conditions are at special risk of infection because their immune systems are already weak. Thus, Board oversight of safety at the Sturgis Facility takes on an even greater relevance as lapses in such are ever more consequential in terms of the dire risks they pose to the health and safety of infants, and to the magnitude of financial risks posed to the Company.

76. Infants are born with underdeveloped immune systems, which makes them particularly susceptible to bacterial infection. As a result of their immature immune systems, newborns are at heightened risk for diseases such as sepsis, pneumonia, and meningitis. The immune system is the body's defense against illness; an underdeveloped immune system has no experience fighting bacteria and cannot mount the effective defense of an older, fully-developed immune system. To compensate for an underdeveloped immune system, full-term infants have some passive immunity from their mothers—during the last few month of pregnancy, the infant receives antibodies from their mother that protect them for the first few months of life. Breastmilk also contains antibodies that confer passive immunity—infants who do not consume breastmilk

have less passive immunity because they do not get those antibodies. Preterm infants are at even greater risk of infection because they lack those maternal antibodies and their immune systems had even less time to develop before birth. Infant formula manufacturers are aware of the importance of producing safe infant formula given the heightened vulnerability to bacterial infection of infants who consume formula.

B. The Federal Special Supplemental Nutrition Program for Women, Infants, and Children

77. Abbott contracts actively and profitably with the federal government's Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC Program"). The WIC Program provides federal funds to state agencies that supply low-income mothers and infants at nutritional risk with vouchers they can use to purchase nutritional items including powdered (but not ready-to-feed) infant formula. It serves more than forty percent of the country's infants (1.2 million infants per year), and accounts for more than half of all formula consumption. Between 2019 and 2022, the WIC Program served an average of 1.4 to 1.6 million infants per year.

78. In order to participate in the WIC Program, infant formula manufacturers must comply with the provisions of the FDCA and federal regulations governing manufacturing, quality control, and recordkeeping.

79. If selected by a state's WIC agency, the formula manufacturer is awarded market exclusivity for each state's WIC Program. Each state agency WIC Program uses federal funds to negotiate infant formula rebate contracts with manufacturers like Abbott through a competitive bidding process. Any savings from the rebate contracts fund the food portion of the WIC grant, enabling the WIC Program to serve more recipients. The formula manufacturer that offers the highest discount on wholesale prices wins the contract. States are incentivized to award manufacturers market exclusivity, rather than let multiple manufacturers participate in WIC,

because the competitive bidding earns states higher rebates. A mother using the WIC Program receives vouchers to purchase formula from the winning formula manufacturer only; the voucher cannot be used to purchase formula from other companies.

80. Abbott has participated in the WIC Program since the program began in 1972. Abbott is the sole supplier for the WIC Program in thirty-four states and Washington, D.C., four territories, and six Indian tribal organizations, or approximately half of the 1.2 million infants who receive formula through the WIC Program every year. This means that half of all WIC recipients can *only use their benefits to purchase Abbott formula*.

81. In addition to capturing the whole WIC market in the state, the same manufacturer can gain up to eighty-five percent of the state's powdered infant formula market. This spillover effect can occur for a number of reasons: doctors may recommend the WIC contract brand to all formula-fed babies; hospitals may provide the WIC contract brand to all new mothers so that WIC mothers do not have to switch formula after leaving the hospital; and WIC-authorized stores must keep a minimum stock of the WIC contract brand and often devote more shelf space and visibility to that company's products. Manufacturers prize these non-WIC sales because they can yield up to six times the revenue of WIC formula purchases. The WIC designation also helps formula manufacturers beyond direct sales by increasing the price of infant formula overall and increasing the popularity of the supplemented formula included in WIC packages.

82. The WIC Program's sole-source contract model drives the highly concentrated nature of the U.S. formula market because it reduces the competitiveness and flexibility of that market. Three companies—Abbott, Mead Johnson, and Nestlé—make up 90% of the country's infant formula market.

C. Safe Production of Infant Formula

1. Bacteria, Cronobacter In Particular, Poses A Life-Threatening Risk to Infants.

83. Abbott is well aware that contaminated infant formula generally, and cronobacter contaminations specifically, pose life-threatening risks to infants.

84. Cronobacter bacteria is life threatening to infants, even when treated quickly. Cronobacter commonly causes meningitis, a swelling of the linings around the brain and spinal cord, and sepsis, a blood infection. Infants infected with cronobacter have a mortality rate of up to eighty percent. Indeed, an infant infected with cronobacter can die just hours after the onset of symptoms. Infants who survive a cronobacter infection often suffer neurological problems, including delayed brain development, brain abscesses, or hydrocephalus, a buildup of fluid inside the brain.

85. Powdered infant formula contaminated with cronobacter is the source of more than ninety percent of cronobacter infections in infants. Infant formula is particularly susceptible to cronobacter contamination because the bacteria is unusually resistant to an end-stage step in the manufacturing process, called the "kill step," discussed further below. Cronobacter can also survive in a finished can of formula for up to a year.

86. Other bacteria in infant formula pose hazards to infants. Microorganisms and salmonella may cause gastrointestinal illness, including diarrhea, high fever, aches, headaches, lethargy, a rash, blood in the urine or stool, and are often fatal. Infants are at special risk of complications, including for salmonella meningitis, which has a high fatality rate and a significant rate of neurologic complications.

2. Cronobacter and Salmonella Risks In Infant Formula

87. Given the extraordinary seriousness of infant infection, the FDA requires that ***every batch*** of powdered infant formula be tested for cronobacter and salmonella before it is released. As reported by *The Washington Post*, the requirement was established after Abbott admitted in a 2003 meeting with U.S. Department of Agriculture, FDA, and Center for Disease Control ("CDC") officials, that cronobacter was "***a little bit more ubiquitous***"[12] in powdered formula production than Abbott previously thought and claimed that there was no way to sterilize the powder to reduce the risk of contamination or infection.

88. In fact, formula manufacturers like Abbott know that infant formula manufacturing is "a breeding ground" for cronobacter. The bacteria is unusually resistant to heating, drying, and disinfectant and can survive in infant formula for up to a year.

89. Cronobacter and other bacteria can contaminate powdered infant formula at a number of points during the manufacturing process. These include: (a) contaminated raw ingredients, (b) ineffective heating, (c) spray drying, and (d) cross contamination during filling (via lax hygiene and cleaning practices, improper equipment maintenance, and standing water).

a. *Ineffective heating*: At the heating stage, the most important "kill step" in the manufacturing process, the formula is heated to temperatures designed to kill off pathogens (bacteria or other microorganisms that can cause disease), including cronobacter. Cronobacter can survive the heating stage if the powder is not heated to the appropriate temperature.

b. *Spray drying*: Following the heating stage, formula is piped in as a liquid to "spray balls," which distribute it as an aerosol into a dryer. Cronobacter can contaminate

[12] Bold and italicized text indicates emphasis added, unless otherwise indicated.

formula at this stage if the pipes that deliver the liquid to the spray balls, the "spray balls" themselves, or the dryers are improperly maintained or cleaned, and harbor bacteria.

c. *Cross contamination*: Following the drying stage, formula is filled into cans for distribution. Cronobacter can contaminate formula at this stage via the movement of air, milk powder dust particles, contaminated equipment, and personnel. The risk of cross contamination is especially high in powdered milk production environments.

3. FDA Regulations Hold Manufacturers Like Abbott Responsible For Infant Formula Safety.

90. The regulatory regime puts the onus of creating safe food product on the manufacturer, not the regulator. The modern FDA was born in 1906 when the Federal Food and Drugs Act added regulatory functions to the agency's scientific mission. The FDA is responsible for regulating everything from tobacco products to human and veterinary drugs, medical devices to cosmetics, human food to products that emit radiation.

91. Beginning in 1980, with the passage of the Infant Formula Act, 21 U.S.C. § 350a, the FDA has regulated the manufacture and labelling of infant formula, including through setting nutrient requirements and quality controls. The Infant Formula Act was passed following a 1979 crisis in which hundreds of infants were diagnosed with hypochloremic metabolic alkalosis—a serious medical condition characterized by low levels of chloride or potassium and whose symptoms included poor appetite, failure to gain weight, diarrhea, and blood in urine—after consuming a brand of infant formula manufactured by Syntex Laboratories. Syntex had recently reformulated its infant formula so that it no longer included adequate amounts of certain nutrients, causing the infants who consumed it to have chemical imbalances. Although Syntex performed a recall, it was dangerously slow, leaving defective product still on store shelves as Congressional hearings into the failure began.

92. Today, federal law and the related federal regulations address every step of the formula manufacturing process and make clear that infant formula manufacturers bear sole responsibility for producing and distributing safe infant formula. *See* 21 U.S.C. § 321 *et seq.*; 21 C.F.R. §§ 106, 107. This regulatory landscape contrasts starkly with that of pharmaceutical drugs. For example, unlike pharmaceuticals, the FDA does not test infant formula before it is marketed, even though the FDA Commissioner recently compared infant formula—and particularly specialty formula—to life-saving medication.

93. Given the regulatory scheme that holds manufacturers responsible for product safety and the serious vulnerability of infants to bacterial infection, manufacturing, and selling infant formula that is free of bacteria and safe for consumption by vulnerable infants is an essential and mission-critical aspect of Abbott's business.

94. Manufacturing safe infant formula requires specific levels of forty different nutrients, some of which can be toxic in excess. The manufacture of powdered infant formula is heavily regulated in order to ensure infants consume safe infant formula that has been properly mixed and not contaminated. Regulatory compliance is especially important to producing safe formula because the FDA explicitly plays a limited oversight role and end-product testing is unlikely to detect contaminations.

95. Federal regulations govern infant formula manufacturing, and any formula that does not comply with current good manufacturing practice ("cGMPs") requirements for infant formula under the FDCA and its implementing regulations is considered "adulterated." *See* 21 U.S.C. § 350a; 21 C.F.R. § 106. The FDCA prohibits the introduction into interstate commerce of adulterated food and violations are punishable by fines or imprisonment. *See* 21 U.S.C. §§ 331, 333. Under the FDCA's implementing regulations, infant formula manufacturers are required to

comply with quality control procedures (21 C.F.R. § 106), recordkeeping and reporting requirements (21 C.F.R. § 106.100), labeling requirements (21 C.F.R. §§ 107.3-107.30), nutrient requirements (21 C.F.R. § 107.100), and recall requirements (21 C.F.R. §§ 107.200-107.280).

96. The cGMPs require an infant formula manufacturer, like Abbott, to implement a system of production and in-process controls that covers "all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product," and "is designed to ensure that an infant formula is manufactured in a manner that will prevent adulteration of the infant formula." 21 C.F.R. § 106.6(a), (b). As such, Abbott was required to:

- establish and monitor specifications for "any point, step, or stage in the production process where control is necessary to prevent adulteration," 21 C.F.R. § 106.6(c);
- "establish a corrective action plan" when its system does not meet these specifications, 21 C.F.R. § 106.6(c); and
- "review and evaluate the public health significance of any deviation" from those specifications. 21 C.F.R. § 106.6(c)(4).

97. The cGMPs require process controls. An individual "qualified by education, training, or experience shall conduct a documented review" of any specifications the manufacturer fails to meet and decide to "reject the affected article, to reprocess or otherwise recondition the affected article, or to approve and release the article for use or distribution." 21 C.F.R. § 106.6(c)(4). The manufacturer shall establish recordkeeping procedures. 21 C.F.R. § 106.6(c)(5).

a. The cGMPs address worker conduct. Formula plant workers must be sufficiently "qualified by education, training, or experience, to perform all operations, including all required recordkeeping, in the manufacture, processing, packing, and holding of" infant formula. 21 C.F.R. § 106.10(a). Workers working directly with infant formula must practice

"good personal hygiene" to prevent contamination, including wearing clean outer garments and practicing proper handwashing. 21 C.F.R. § 106.10(b).

b. The cGMPs mandated that the Sturgis Facility be clean and sanitary. "Buildings used in the manufacture, processing, packing, or holding of infant formula shall be maintained in a clean and sanitary condition and shall have space for the separation of incompatible operations, such as the handling of raw materials, the manufacture of the product, and packaging and labeling operations." 21 C.F.R. § 106.20(a).

c. The cGMPs require that Abbott ensure its equipment related to temperature, moisture, and water activity is properly maintained. 21 C.F.R. § 106.30(d). The manufacturer shall "ensure that equipment and utensils used in the manufacture of infant formula are cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula" and that the cleaning is reviewed by a qualified individual and recorded. 21 C.F.R. § 106.30(f).

d. The cGMPs provide specifications to Abbott about the ingredients, containers, and closures for infant formula. When these specifications are not met, a qualified individual shall conduct a documented review and determine whether the failure could result in adulterated formula, and decide to reject, reprocess, or approve the affected formula for use. 21 C.F.R. § 106.40(d). The guidelines mandate that Abbott "shall not reprocess or otherwise recondition an ingredient, container, or closure rejected because it is contaminated with microorganisms of public health significance or other contaminants, such as heavy metals." 21 C.F.R. § 106.40(d).

e. The cGMPs focus on the manufacturing process. Specifically, Abbott is required to maintain complete records relating to the production and control of infant formula

and establish a system to identify the processing stage and unique identification number for a particular production unit of formula. 21 C.F.R. §§ 106.50(a), (c). The manufacturer shall establish controls to maintain the nutrient levels and prevent contamination with microorganisms or other contaminants, including the spray drying process, removal of air from the finished product, and proper sealing. 21 C.F.R. § 106.50(d).

f. The cGMPs mandate that Abbott prevent adulteration from microorganisms, including cronobacter and salmonella. A manufacturer "shall test representative samples of each production aggregate of powdered infant formula at the final product stage, before distribution, to ensure that each production aggregate meets the microbiological quality standards." 21 C.F.R. § 106.55(c). Formula containing microorganisms in violation of the quality standards "shall be deemed adulterated." 21 C.F.R. § 106.55(e).

g. In the event Abbott identifies formula containing microorganisms or bacteria, the cGMPs mandate that it, as manufacturer, quarantine infant formula "until it determines that the production aggregate meets all of the manufacturer's specifications" including those on microbiological contamination and quality control procedures, "or until the documented review of the failure to meet any of the manufacturer's specifications finds that the failure does not result in, or could not lead to, adulteration of the product." 21 C.F.R. § 106.70(a).

h. Further, the cGMPs require infant formula to be traceable with a sequential number "that identifies the product and the establishment where the product was packed and that permits tracing of all stages of manufacture of that production aggregate, including the year, the days of the year, and the period during those days that the product was packed, and the receipt and handling of raw materials used." 21 C.F.R. § 106.80.

98. In sum, Abbott bears the ultimate legal responsibility for producing formula that is safe for infant consumption. 21 U.S.C. §§ 331(a)-(b), 333(a). The FDA, which only inspects infant formula plants once a year and does not test infant formula before it is marketed, plays an extremely limited role in overseeing the manufacture, sale, and distribution of infant formula. Once the infant formula is on the market, the FDA relies exclusively on manufacturers to produce safe infant formula.

99. The FDA's "yearly inspection of all facilities that manufacture infant formula" is limited and predictable. As part of the inspection, the FDA collects and analyzes samples of the infant formula. Indeed, the FDA visited the Sturgis Facility once a year in September, for between four and eight days. At the conclusion of an FDA inspection, the agency issues an Inspection Report to the company, which it discusses with those most responsible for the facility. Following each FDA inspection, the agency discussed its Inspection Report with the Sturgis site director. In 2019, the Sturgis Site Director was Patrick A. Cooper. In 2021 and 2022, the Site Director was TJ Hathaway.

100. If the FDA inspectors "observe any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act [of 1938] and related Acts," such as failures to adhere to the cGMPs, the FDA issues the facility a Form 483 Letter directed to the site's senior management.

101. A Form 483 Letter "notifies the company's management of objectionable conditions" that indicate that a food is "adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health." Following the inspection, the FDA meets with senior site management to go over the Form 483 observations.

The company may notify the FDA of whether it plans to take corrective action and, if so, what kind.

102. As described further below, the FDA issued Abbott a Form 483 letter after each of its three site inspections of Sturgis—in 2019, 2021, and 2022. The FDA did not inspect Sturgis in 2020 due to the COVID-19 pandemic.

103. The FDA may also issue a "Warning Letter" when it finds that a manufacturer has "significantly violated FDA regulations." FDA Warning Letters identify the violation, require the company to correct the problem, and set directions and a timeline for the company to notify the FDA of its corrective action plan. Following the Warning Letter, the FDA checks that the company's corrective action was adequate to resolving the violation.

104. Regulatory compliance is especially important to ensuring that Abbott is producing safe infant formula because end product testing is not likely to detect contaminations. In testimony to the U.S. Senate on the Abbott Formula Recall and Sturgis Shutdown, FDA Commissioner Robert M. Califf acknowledged that "[i]t is well documented in the scientific literature, however, that end product testing is unlikely to detect low levels of contamination." This is because cronobacter tends to clump together in formula containers so that a single sample might test negative despite the presence of cronobacter in the container. Additionally, manufacturers test a very small fraction of the product they produce.

105. Because end product testing is unlikely to detect contaminations, a positive cronobacter sample of finished product may indicate a major contamination event.

4. Abbott Lobbied For Less Regulatory Oversight of Infant Formula Manufacturing.

106. Over the last decade, Abbott repeatedly lobbied the U.S. government to reduce the amount of government oversight and regulation of infant formula manufacture and sale.

107. For example, in 2014, in response to proposed FDA rules that would increase regular safety inspections of plants used to manufacture infant formula, a lobbying group representing Abbott, the Infant Nutrition Council of America (then called the International Formula Council), sought to weaken FDA proposed regulations meant to prevent salmonella and cronobacter contaminations in infant formula. The group argued that the FDA "overestimate[d] the incidence of cronobacter infection" by relying on "outdated data." Following the group's input, the final FDA rule reduced the frequency for required testing of new infant formula and exempted manufacturers from that testing upon a showing that the new formula would not differ from formula that had already undergone the required testing.

108. Later that same year, the lobbying group petitioned the FDA to further weaken the bacteria safety testing standards, including by reducing the frequency of inspections. The lobbying group claimed that increased testing of formula would have "no corresponding public health benefit," while decrying the compliance costs to formula manufacturers (including personnel and lab fees).

V. ABBOTT LACKED ANY BOARD-LEVEL OVERSIGHT OF INFANT FORMULA SAFETY AT STURGIS.

109. The Director and Officer Defendants breached their fiduciary duty of oversight by utterly failing to create and maintain a reasonable information and reporting system that would apprise the Board of safety issues with Abbott's infant formula business. As described above, safely manufacturing infant formula is particularly essential and mission critical for Abbott because those formulas are consumed by a vulnerable population with no inherent immunity to protect against potentially fatal bacterial infections. Because the Board did not have a system that provided timely, accurate information about the safety of its infant formula, Abbott's Board was disabled from responding to risks when they arose.

110. Abbott management, including the Officer Defendants, were made aware of severe bacterial contaminations at the Sturgis Facility over a period of several years, including through annual FDA inspections. The Officer Defendants failed to correct them, and [redacted]

111. Indeed, as detailed herein, Abbott's Board materials reflect that [redacted]

112. Abbott's Board was unable to address and respond to severe safety issues with the Company's infant formula because Defendants had failed to establish a reasonable system of regular safety reports to the Board. As a result, when the Sturgis Facility fell into disrepair, endangering the safety of all infants who consumed formula manufactured at the Facility and exposing the Company to significant business risk, [redacted]

A. Abbott's Public Policy Committee Utterly Failed to Learn Any Relevant Safety Information About Sturgis.

113. Abbott's Public Policy Committee is nominally tasked with overseeing "regulatory" issues facing the Company. [redacted]

[redacted]

114. According to its charter, the Public Policy Committee is responsible for "maintaining legal, regulatory and healthcare compliance" at Abbott.[13] The Charter does not mention the word "safety." It does not require that the Committee receive reports about the safety of the Company's products. Instead, the Charter by its own terms has a myopic and cramped focus on *regulatory or legal* compliance. No other Committee of the Board oversees product safety.

115. In practice, this meant that [redacted] An FDA Warning Letter is reserved for "violations of regulatory significance." Thus, [redacted]

[13] ABBOTT, PUBLIC POLICY COMMITTEE CHARTER, https://dam.abbott.com/en-us/documents/pdfs/investors/Public-Policy-Committee-Charter.pdf.

116. [redacted] Abbott's Board could not in good faith rely wholly on FDA regulation to ensure the safety of the Company's infant formula, and as described above, the core responsibilities for infant formula safety reside with the Company, not the FDA.

117. The information-reporting system also relied on Abbott employees to convey accurate information to the FDA during its inspections. As detailed below, Abbott's employees deliberately hid problems from FDA inspectors with the goal of preventing the FDA from discovering the "egregiously unsanitary" condition of the Facility. The Board could not solely rely on the FDA to ensure infant formula given this culture at its Sturgis Facility.

118. [redacted]

119. [redacted]

120. [redacted]

[redacted]

121. [redacted]

122. [redacted]

123. [redacted]

124. The Board breached its fiduciary duty to establish an information reporting system that actually provided it information concerning the safe manufacture of Abbott's products. [redacted]

B. The Board Had No Whistleblower Reporting System.

125. A system of reporting that elevates whistleblower reports to the Board is one hallmark of effective oversight. [redacted]

126. [redacted]

127. Whistleblowers are particularly important to food manufacturers, a position that Congress took through the Food Safety Modernization Act, 21 U.S.C. § 399d, when it established strong whistleblower protections for employees of entities, like Abbott, engaged in the "manufacture, processing, packing, transporting, distribution, reception, holding, or importation of food." *Id.* at (a). This statute provides protections for whistleblowers and requires specific deadlines for whistleblowers to submit complaints. *Id.* at (b)(1).

C. [redacted]

128. [redacted]

129. [redacted]

130. [redacted]

131. [redacted]

[redacted] Because the Board had not made a good faith effort to implement a system of controls to oversee infant formula safety, Directors remained uninformed and disengaged as the Company sifted through complaints, identified trends, and shared this information with regulators.

D. Defendants' Systematic Failure to Exercise Oversight Meant the Board Remained In the Dark About the "Egregiously Unsanitary" Conditions at Sturgis.

132. Because Defendants did not establish and maintain a system of timely reporting on the safety of its products, the Directors remained in the dark for years as a myriad of serious safety, health, and cleanliness issues of mission-critical importance compounded at the Sturgis Facility. The failure to implement a board-level system of controls that allowed Directors to effectively oversee product safety and quality breached, and continues to breach, Defendants' fiduciary duties to the Company.

1. Throughout 2019: Abbott Received Complaints About Infants Sickened After Consuming Infant Formula From Sturgis.

133. Throughout 2019, Abbott was made aware of complaints that infants had become sick after consuming infant formula from Sturgis. For example, that year Abbott "received a complaint from a nurse practitioner about five babies who had consumed Similac Sensitive formula and were projectile vomiting for reasons that were not clear. A baby with confirmed cronobacter was having seizures after consuming three types of Similac[.]"

134. In response to these medical events, Abbott reviewed its consumer complaint records and, upon finding no other medical complaints had been made about the particular batches of formula identified by the nurse, closed the investigation without further inquiry.[14]

[14] FDA, ESTABLISHMENT INSPECTION REPORT, ABBOTT NUTRITION, STURGIS, MI 15 (2019).

2. August and September 2019: Sturgis Produced Infant Formula Contaminated with Cronobacter.

135. On August 13, 2019, Abbott's internal lab confirmed a positive test for cronobacter in a finished batch of Alimentum Advance Powder, a "hypoallergenic" powdered infant formula for babies with allergies, including a lactose sensitivity.[15] Abbott determined the root cause to be a "non-routine intervention" and told the FDA it planned to destroy the batch.[16]

136. Just one month later, on September 25, 2019, Abbott's internal lab confirmed a second positive test for cronobacter in another finished batch of powdered infant formula.[17] The 2021 FDA Inspection Report summarized the findings, stating "the root cause was determined to be environmental" and the "affected batch was destroyed."[18] In other words, the source of the contamination was located within the manufacturing facility. There is no indication that Abbott conducted a more holistic analysis to determine whether there were other cronobacter issues.

137. [redacted] The Board's failure to implement reporting systems ensuring it received timely information about risks in the Company's infant formula division allowed the bacterial contamination to continue throughout the Sturgis Facility.

[15] *Id.* at 19.
[16] *Id.*
[17] FDA, ESTABLISHMENT INSPECTION REPORT, ABBOTT NUTRITION, STURGIS, MI 19 (2021).
[18] *Id.*

3. September 2019: Abbott Recalled Infant Formula Produced At Sturgis For "Seam Integrity" Problems.

138. Despite two instances of bacterial contamination at Sturgis in the summer of 2019, Abbott took no steps to investigate or improve safety compliance at the facility. Instead, safety compliance deteriorated. On September 13, 2019, days before the FDA was set to arrive for its 2019 annual inspection, Abbott instituted a limited recall of several batches of Calcilo XD, a specialty powdered formula produced by Abbott for infants with certain conditions, including hypercalcemia. The recall was necessary because discolored powder was stuck on the seam on Abbott's formula cans, causing a rancid smell.

139. Powder stuck in the seam of a can suggests the seal on the can is not as tight as necessary. Problems with the seam of a can are referred to as "seam integrity" issues. Seam integrity is particularly problematic for dry powdered formula production, because improperly sealed cans allow air, moisture, and bacteria into the can of formula.

140. Abbott should have addressed the "seam integrity" issues with the formula cans following the Calcilo XD recall, including increasing seam testing. Rather than increase testing and seek out the root cause of the "seam integrity" issues, as the Sturgis Whistleblower alleged in their October 2021 complaint, Sturgis management directed that seam checks be performed on *empty cans*. Conducting a seam check of an empty can be ineffective because seam integrity issues are caused by the existence of powder on the rim of the can, which impacts the seam. As the Sturgis Whistleblower explained in their October 2021 complaint, "[p]erforming seam checks on empty cans was the only way to achieve passing results without finding powder in the seam." Indeed, instead of "tearing down" cans to check for powder in the seams, Sturgis management directed operators to weigh each can to show the correct amount of powder was in the can, even though this method can lead to inaccurate test results. According to the Sturgis Whistleblower,

"[t]hese decisions were made because leadership knew powder would be found in the seam. They did not want to discard the entire batch."

141. Abbott's purposely inaccurate testing for seam integrity issues violate the Company's regulatory obligations to "maintain the records specified in this regulation in order to permit the Food and Drug Administration to determine whether each manufacturer is in compliance with Section 412 of the [FDCA]." 21 CFR § 106.100(a).

142. [redacted]

4. Summer 2019: Sturgis Produced Infant Formula Contaminated With Microorganisms.

143. The Sturgis Whistleblower alleged that in the summer of 2019, Abbott's testing of a finished batch of powdered infant formula tested positive for microorganisms ("micros"). Micros is a catchall term for bacteria, including pathogens like cronobacter. A positive test for micros in finished product suggests a wider contamination risk across products and throughout the manufacturing facility.

144. According to the Sturgis Whistleblower, Abbott first detected the micros through standard batch testing when it tested ten samples pulled evenly throughout the batch. It then pulled just fifteen additional samples for further testing. Those additional samples again tested positive for micros. Instead of undertaking a more thorough testing procedure, putting the whole

batch on hold or destroying it, Abbott decided to perform a time code removal, meaning that it only removed product made within a certain limited time period.

145. Abbott did not perform additional testing to ensure that all of the micro-positive product was captured and destroyed. In other words, Abbott distributed and sold formula from a batch that tested positive for micros ***without being sure that the released product did not contain micros***. As the Sturgis Whistleblower put it, "[t]he infant formula was released commercially without supporting documentation to suggest it was compliant and safe for consumption."

146. The safety issues that caused the micros batch were emblematic of the Sturgis Facility falling into disrepair without an appropriate response. The micros batch resulted from Sturgis's drying process relying on aging infrastructure, specifically product flow pipes that were, according to the Sturgis Whistleblower, "pitting and leaving pin holes." This allowed bacteria to enter into the holes. Moldy spray dryers are among the most common contamination sources for infant formula. Nevertheless, Sturgis's clean-in-place washes, the mechanism to clean out these sorts of micros from the pipes, also failed.

147. In 2019, according to the Sturgis Whistleblower, an electrical shortage caused some of the "spray balls"—which distribute cleaning chemicals into the processing equipment to clean them out—to malfunction. Thus, instead of cleaning the equipment, the "spray balls" were "covered in caked-on moldy product."

148. Potential contamination by way of moldy spray dryers pre-dated the 2019 micros contamination, and continued for years thereafter. In 2022, in a finding that validated the Sturgis Whistleblower's allegations, the FDA discovered that Abbott records detailed a history of deterioration of spray dryers dating back to September 2018, and that same damage still existed over three years later.

149. Even so, the damage was more widespread than Abbott records acknowledged. In May 2022, the DoJ's complaint stated that the cronobacter-contaminated batches of infant formula produced at Sturgis in August 2019 and June 2020 were processed on different dryer and filling lines than those originally identified in 2018. This suggested that Abbott had not only failed to fix the problem, but that it had gotten significantly worse over time.

150. [redacted]

5. September 2019: FDA Inspection Of Sturgis Resulted In A Form 483 Letter Regarding Insufficient Product Testing.

151. [redacted]

152. The FDA conducted its annual 2019 inspection of Sturgis between September 16 and 24, 2019. According to the Sturgis Whistleblower, rather than addressing the unsafe conditions that had led to micros, cronobacter, and the recall earlier in the year, Sturgis management sought to hide those conditions from the FDA.

153. In particular, Sturgis employees actively sought to keep the FDA from learning that micros had been found at the facility earlier in the year, and that Abbott distributed and sold finished infant formula without first ensuring that it was not contaminated with micros. To do that, Sturgis management "sanitized" records before furnishing them to inspectors.

154. Later, according to the Sturgis Whistleblower, a senior Quality Assurance official acknowledged the awkwardness of having to avoid providing direct answers to the FDA.

155. As a result of this conduct, the FDA did not discover evidence of the micro batches during its inspection. According to the Sturgis Whistleblower, a member of "management stated that the FDA was on the 'right trail' [and] … volunteered that she was amazed that the FDA was unable to discover what occurred with the micro batches."

156. Sturgis staff and department managers congratulated each other when what they considered a successful audit was over.

157. The FDA made other findings at the September 2019 inspection, however, and issued a Form 483 letter to the Company after the Sturgis inspection concluded. The letter, shared with Sturgis Site Director Patrick A. Cooper, said that Abbott's internal testing violated the microbiological testing requirements under 21 C.F.R. § 105.55(c) because Abbott did not conduct sufficient testing of finished infant formula product "at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards."[19]

158. The FDA's September 2019 Inspection Report also noted that Abbott had received complaints about infants who became ill after consuming formula from Sturgis, as described above.[20]

159. [redacted]

[19] FDA ESTABLISHMENT INSPECTION REPORT, ABBOTT NUTRITION, STURGIS, MI 18 (2021).
[20] FDA ESTABLISHMENT INSPECTION REPORT, ABBOTT NUTRITION, STURGIS, MI 15-17 (2019).

[redacted][21]

6. 2020 Through 2022: Sturgis Experienced Persistent Standing Water, Creating a Breeding Ground for Bacteria Like Cronobacter.

160. Between January 2020 and January 2022, Abbott had documented ***a total of 310 leaks, standing water, and condensation*** at the Sturgis Facility.[22] Some of these water issues were caused by reoccurring leaks from the facility's roof in February 2021, November 2021, and again in January 2022 (shortly before the Facility was shut down).[23] Moisture of any kind is a risk factor in a powdered infant formula plant, because it presents a breeding ground for bacteria.

161. The FDA identified standing water as a problem following its 2021 and 2022 inspections.[24] And water and moisture were among the myriad problems identified in the Consent Decree. As the Consent Decree explained, "[t]he uncontrolled wet environment in process areas, in conjunction with the presence of cronobacter and deteriorating equipment that enables harborage of cronobacter (i.e., cracks in food-contact surfaces of equipment, as described above), ***create an unacceptable risk of bacterial contamination of [Abbott's] products***."[25]

162. [redacted]

[21] FDA, FORM 483 LETTER TO ABBOTT NUTRITION, STURGIS, MI 4 (2022).
[22] *Id*.
[23] DoJ Complaint, at ¶ 41(a).
[24] FDA, FORM 483 LETTER TO ABBOTT NUTRITION, STURGIS, MI 4 (2022).
[25] DoJ Complaint, at ¶ 40.

[redacted]

7. June 2020: Sturgis Manufactured Infant Formula Contaminated With Cronobacter.

163. On or about June 12, 2020, less than a year after Abbott first identified cronobacter in finished infant formula product, Sturgis's internal product testing revealed another batch of infant formula contaminated with cronobacter.[26] The contaminated formula had not yet been distributed; Abbott destroyed it.[27] However, the FDA noted that Sturgis did not discover the root cause of the contamination.[28]

164. The June 2020 positive cronobacter test occurred in infant formula that had been processed on different equipment (i.e., different spray driers and different filling lines)[29] than the August 2019 contamination. This was significant because, as the DoJ later explained, "[t]he presence of *Cronobacter spp.* on different processing equipment at different times indicates the possibility of multiple avenues for spreading bacterial contamination in the manufacturing environment."[30]

165. Thus, the June 2020 cronobacter contamination in finished (ready to distribute) powdered infant formula product suggested widespread bacterial contamination in the Facility, and evidenced widespread safety and compliance failures at Sturgis. Because Defendants failed in

[26] *See id.* at ¶ 6.
[27] FDA ESTABLISHMENT INSPECTION REPORT, ABBOTT NUTRITION, STURGIS, MI 19 (2021).
[28] *Id.*
[29] As the DoJ explained, "[s]pray dryers process infant formula or other food from a liquid form to powder form; this process is known as 'drying.' Filling lines are used for putting infant formula or other food into containers and sealing the containers." DoJ Complaint, at ¶ 40.
[30] *Id.* at ¶ 6.

their oversight responsibility to establish an adequate system of reporting, Directors did not know that deadly bacteria was spreading at the Sturgis Facility.

166. [redacted]

167. The FDA did not inspect Sturgis in 2020, as it usually would. [redacted]

8. August 2020: Further Seam Integrity Issues Plagued Sturgis, And Management Allowed Potentially-Contaminated Product To Remain On the Market.

168. According to the Sturgis Whistleblower, as it had the year prior, with the 2019 microorganisms contamination, in the summer of 2020, Sturgis management manufactured, distributed, and sold formula that it knew might be contaminated.

169. In August 2020, less than a year after seam integrity issues were discovered with powdered infant formula cans, Sturgis's internal testing discovered additional seam integrity problems in multiple batches of Similac Sensitive for Spit-Up, a ready-to-feed (i.e., non-powdered) formula meant for infants with a tendency to spit-up.

170. Abbott detected the problem *after* some of the ready-to-feed formula had been shipped for distribution. Sturgis management did not recall the already-shipped product. Instead, according to the Sturgis Whistleblower, management "intentionally misrepresented the severity of the issue to division officials," who were required to be notified that a nonconforming product had been released. Product that had not yet shipped was destroyed, which further suggested the entire batch (including that which had already shipped) was non-compliant and/or unsafe for consumption.

171. [redacted]

9. February 16, 2021: The Sturgis Whistleblower Filed The OSHA Complaint.

172. On February 16, 2021, the Sturgis Whistleblower filed a complaint, pursuant to the Food Safety Modernization Act, with the Department of Labor's OSHA about safety violations at the Sturgis Facility, including a number of the items discussed above. The Company received a copy of the OSHA complaint that month, and responded to OSHA two months later in April 2021. [redacted]

[redacted]

173. Per a copy of the OSHA whistleblower complaint obtained through Plaintiff's public records requests, the Sturgis Whistleblower raised several of the 2019 product safety and quality issues detailed above, including the following six critical failures:

a. *First*, as detailed above, in 2019, the micros event occurred because, in the Sturgis Whistleblower's view, Sturgis lacked "someone of sufficient experience or training conducting a [clean-in-place] process" (the process for cleaning equipment and the production area); Sturgis workers failed to review a clean-in-place chart indicating that spray balls were "covered in caked-on moldy product;" and for "several years, some of the equipment associated with the drying process at the Sturgis Site was failing and in need of repair." This allowed bacteria to enter the system." *See supra* Section V.D.4.

b. *Second*, the Sturgis Whistleblower further identified grave "FDA compliance issues," such as Abbott improperly releasing batches that may have been contaminated with micros for distribution, when the Company should have destroyed the entire batch. *See supra* Section V.D.4.

c. *Third*, the Sturgis Whistleblower detailed the efforts that Sturgis employees made to hide the micros event from the FDA during its 2019 inspection. *See supra* Section V.D.5.

d. *Fourth*, the Sturgis Whistleblower described the 2019 seam integrity problem with the powdered Calcilo XD formula. The Sturgis Whistleblower alleged that they

had raised the issue of testing empty cans to Sturgis employees, but "the issue was not resolved and only covered up" by Sturgis management. *See supra* Section V.D.3.

e. *Fifth*, the Sturgis Whistleblower described the August 2020 seam integrity problems with the ready-to-feed formula Similac Sensitive for Spit-Up, and Abbott's failure to recall potentially contaminated product. *See supra* Section V.D.8.

f. *Sixth*, the Sturgis Whistleblower alleged that, in 2019, Abbott produced cans of ready-to-feed infant formula with less than the eight ounces of liquid, known as low-fill weights, at the Facility in violation of 21 C.F.R. § 107(g) which requires that the net quantity of contents "accurately reveal the quantity of food in the package." When Sturgis management discovered the issue, rather than remove the underweight cans, they spread cases of under-filled product among the larger batch through the unstacking and restacking pallets of the finished product (a tactic called "shuffling the deck" meant to avoid detection of the under-filled cans). The Sturgis Whistleblower alleged that one member of Quality Assurance leadership "went so far to suggest the criminality of the [redacted's] conduct." While under-filled cans do not constitute a product safety issue, it calls into question the integrity of the Company's formula product. Further, the allegations of Sturgis management disregarding regulations and covering up wrongdoing reveal a problematic approach to regulatory oversight at the Facility.

174. The 2022 FDA Form 483 would ultimately substantiate the Sturgis Whistleblower's report.[31] Yet, Abbott stonewalled the Whistleblower. According to Abbott, "[the Company] investigated the federal OSHA complaint and [had] not been able to confirm the allegations." However, there is no public information about what Abbott did to "investigate the federal OSHA complaint."

[31] FDA, FORM 483 LETTER TO ABBOTT NUTRITION, STURGIS, MI 4 (2022).

175. Even *after* the Abbott Formula Recall and Sturgis Shutdown, Abbott continued to deny the Sturgis Whistleblower's allegations. On June 8, 2022, the *Wall Street Journal* published an article where an Abbott spokesman characterized the federal OSHA complaint as "an escalation of the Michigan OSHA complaint. It continued a pattern of ever-evolving, ever-escalating allegations." This non-substantive response to the Sturgis Whistleblower's complaint demonstrates the Company's refusal to grapple with the serious allegations of widespread misconduct at Sturgis.

176. Abbott's failure to seriously consider or address the Sturgis Whistleblower's complaint is further revealed by the fact that the Company submitted an incorrect timeline of events ahead of Calamari's May 2022 Congressional testimony. The Company only acknowledged receiving the Sturgis Whistleblower's subsequent ***October 2021*** complaint to the FDA (discussed further below), not the ***February 2021*** OSHA complaint. [redacted]

177. [redacted]

[redacted][32]

178. [redacted][33] This failure to obtain timely information through its information-reporting system was a breach of the Board's fiduciary duties.

10. September 2021: The FDA's Inspection Revealed Numerous Quality and Safety Violations.

179. The FDA inspected the Sturgis Facility between September 20 and September 24, 2021, and concluded in its Form 483 that Abbott failed to maintain the Facility "in a clean and sanitary condition," in violation of the cGMPs.[34] The FDA issued Abbott a Form 483 letter detailing the violations and failures it found, including standing water in various locations throughout the Facility; workers failing to observe properly wash their hands; a worker reaching

[32] [redacted]

[33] Abbott redacted [redacted] on the basis of the attorney-client privilege.

[34] FDA, FORM 483 LETTER TO ABBOTT NUTRITION, STURGIS, MI 1 (2021).

into essential ingredient without cleaning their hands or gloves; [redacted] Further, the September 2021 FDA findings corroborate the Sturgis Whistleblower's February 2021 OSHA complaint that [redacted] As discussed below, [redacted]

11. September 2021: Abbott Was Made Aware of Numerous Reports of Infants Sickened After Consuming Formula Manufactured At Sturgis.

180. Abbott was on notice of numerous complaints, sent directly to Abbott and to the FDA, of infants becoming sick after consuming Abbott's infant formula. These complaints, spanning 2019 through 2021, were detailed in the September 2021 FDA Inspection Report. According to the Inspection Report, Abbott was made aware of ***at least sixteen complaints*** of infants who became sick with cronobacter and/or salmonella infections after consuming Abbott formula between 2019 and 2021.[35]

181. Abbott's [redacted] complaint monitoring system identified at least ten nurses and parents who observed infants becoming sick after consuming Abbott's formula, including "projectile vomiting," from Similac Sensitive Infant Formula. For example, in September 2019, Abbott learned of an infant who was "hospitalized with colon/intestine infection" after consuming Abbott's formula. Abbott's investigation of the complaint revealed bacteria that indicated a contamination risk in the dryer.

182. In September 2021, while the FDA was conducting its on-site inspection at Sturgis, the agency received a report about an infant in Minnesota who was hospitalized with a

[35] FDA, ESTABLISHMENT INSPECTION REPORT, ABBOTT NUTRITION, STURGIS, MI 27 (2021).

cronobacter infection after consuming Abbott's formula. The infant was hospitalized for twenty-two days.

183. [redacted]

12. October 2021: The Sturgis Whistleblower Filed A Second Whistleblower Complaint, This Time With The FDA.

184. Eight months after filing a whistleblower complaint with OSHA, the Sturgis Whistleblower filed a separate complaint with the FDA. This complaint contained the same sum and substance as the February 2021 complaint to OSHA to which Abbott responded. *See supra* Section V.D.9.

185. Again, Abbott failed to substantively respond to the Sturgis Whistleblower's reports. Further, [redacted]

13. December 2021: Abbott Was Aware of Numerous Consumer Complaints of Infants Sickened With Cronobacter.

186. On December 1, 2021, Abbott and the FDA received a report of an infant who had arrived at an emergency room in cardiac arrest (the report is reflected on the FDA's Form 483

findings for the January 2022 inspection).[36] The infant was sick with a cronobacter infection after consuming Abbott's Similac Pro-Total Comfort (Powder) infant formula. The infant subsequently died.

187. [redacted]

188. [redacted]

189. [redacted]

[36] FDA, FORM 483 LETTER TO ABBOTT NUTRITION, STURGIS, MI 6 (2022).

14. January 2022: Due to Reports of Sick Infants, The FDA Conducted A For-Cause Inspection Of Sturgis Which Revealed "Egregiously Unsanitary" Conditions And Widespread Cronobacter Contamination.

190. On December 30, 2021, the FDA notified Abbott that it would conduct a "for-cause" out-of-cycle inspection of Sturgis in early January 2022 "due to consumer complaints of infant illnesses following consumption of infant formula produced at Abbott's Sturgis facility." The whistleblower complaint the FDA received in October 2021 was also a reason for the for-cause inspection. As the FDA Commissioner explained in later Senate testimony, the FDA initiated inspection planning for a "for-cause" inspection on December 6, 2021, "given the two case complaints [about cronobacter] and the potential severity of *Cronobacter* infections, ***along with a complaint from a former employee at the Sturgis facility***." Abbott responded to the FDA's notice of a for-cause inspection by notifying the FDA of approximately a dozen cases of Covid-19 at the Sturgis Facility, which prompted the FDA to delay beginning the inspection until January 31, 2022.

191. Additional infants became ill as the FDA waited to begin its for-cause inspection. On January 11, 2022, a third infant became ill with a cronobacter infection after consuming Abbott formula. After the inspection began, the FDA learned of a fourth infant infected with cronobacter.

192. [redacted]

193. On February 1 and 2, 2022, the first days of the inspection, the FDA detected cronobacter on multiple surfaces in "medium and high care areas of powdered infant formula

production."[37] This included a finding that the scoop used to fill the formula containers had cronobacter on it. Abbott was effectively scooping cronobacter bacteria directly into formula containers.

194. [redacted]

195. The inspection continued; between February 6 and February 20, 2022, Abbott, working at the FDA's direction, identified cronobacter in various parts of the Facility on ***twenty*** different occasions.[38]

196. Throughout January and into February 2022, Abbott and the FDA learned of sick infants in Minnesota, Ohio, and Texas. As the FDA explained in its consumer advisory announcing the recall on February 17, 2022, its findings reflected "several positive *Cronobacter* results from environmental samples taken by FDA, and adverse inspectional observations by FDA investigators."[39]

197. [redacted]

[37] FDA, FORM 483 LETTER TO ABBOTT NUTRITION, STURGIS, MI 1 (2023).
[38] *Id.* at 3.
[39] Press Release, FDA, *FDA Investigation of Cronobacter Infections: Powdered Infant Formula* (Feb. 17, 2022), https://www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-infections-powdered-infant-formula-february-2022.

E. Abbott Recalled Formula and Shut Down the Sturgis Facility, With No Board Involvement or Oversight.

1. The FDA Pressured Abbott to Shut Down The Sturgis Facility.

198. As the FDA's inspection of Sturgis continued into February 2022, the FDA began preparing for the anticipated harm to the infant formula market if Sturgis were shut down.

199. On February 10, 2022, a day after FDA leadership learned of positive cronobacter samples at Sturgis, the FDA's Food Program Leadership met and the FDA's Coordinated Outbreak Response Network began preparing a response.[40]

200. On February 11, 2022, the FDA "notified the WIC [P]rogram of potential action that could impact the infant formula supply."[41]

201. On February 13, 2022, ***six*** additional samples of cronobacter were discovered at Sturgis.

202. On February 14, 2022, an FDA intra-agency group convened and began "discussions of food safety, regulatory, and supply chain issues related to the response."[42]

203. On February 15, 2022, the FDA "recommend[ed]" to Abbott that it issue a recall at Sturgis. The same day, the FDA found additional cronobacter sample results at the Sturgis Facility.[43]

204. On February 15, 2022, Abbott "voluntarily cease[d] production" at Sturgis and agreed to hold production of certain specialty products only made at Sturgis.[44]

---

[40] FDA, *Timeline of Infant Formula Related Activities*, https://www.fda.gov/media/158737/download.
[41] *Id.*
[42] *Id.*
[43] *Id.*
[44] *Id.*

205. The following day, February 16, 2022, in light of the ongoing findings during the inspection, the FDA again recommended that Abbott institute a recall at Sturgis. The FDA also began "discussion with Abbott Nutrition on additional testing for these held products and a strategy to release products to those in dire need."[45]

206. On February 17, 2022, for the third day in a row, the FDA recommended "that Abbott Nutrition voluntarily recall product,"[46] and simultaneously the FDA issued a consumer advisory warning that "consumers not to use Similac, Alimentum, or EleCare powdered infant formula" from the Sturgis Facility because "it is investigating consumer complaints of *Cronobacter sakazakii* and *Salmonella* Newport" infections linked to Sturgis.[47] The consumer advisory warning noted that the FDA was investigating "complaints of four infant illnesses from three states" and "findings to date include several positive *Cronobacter sakazakii* results from environmental samples taken by the FDA and adverse inspectional observations by the FDA investigators."[48]

207. In the weeklong period leading up to the FDA's consumer advisory warning, as the FDA pressured Abbott to withhold product from distribution and strongly recommended that the Company issue a recall, [redacted]

[45] *Id.*
[46] *Id.*
[47] Press Release, FDA, *FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan* (Feb. 17, 2022), https://www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility.
[48] *Id.*

2. After Days of FDA Pressure, Abbott Recalled Its Sturgis Infant Formula.

208. On February 17, 2022, Abbott announced what it termed a "voluntary" recall of certain products from the Sturgis Facility "after four consumer complaints related to Cronobacter sakazakii or Salmonella Newport in infants who had consumed powder infant formula manufactured in this facility."[49] According to the DoJ's civil complaint filed in May 2022, Randall was responsible for approving the decision made to initiate the Abbott Formula Recall.[50]

[redacted]

209. Abbott's immediate response in its statement announcing the Abbott Formula Recall was to characterize its actions as responsible corporate conduct. It began its statement with three mischaracterizations:

a. *First*, it described the Abbott Formula Recall as something it "initiated." As the FDA's timeline above details, the FDA's for-cause inspection, the repeated and widespread findings of cronobacter at Sturgis, and multiple reports of infant illnesses caused the Abbott Formula Recall.

b. *Second*, Abbott characterized the Abbott Formula Recall as "proactive." To the contrary, Abbott's management ignored myriad safety issues at Sturgis for years. Abbott only announced the Abbott Formula Recall after the FDA, in the middle of a for-cause inspection

[49] Recall Notice, Abbott (Feb. 17, 2022), https://www.similacrecall.com/us/en/home.html#:~:text=2022%20%E2%80%93%20UPDATE%3A%20Abbott%20is%20voluntarily,17.
[50] DoJ Complaint, at ¶ 13.

and on three consecutive days, repeatedly implored it to initiate a recall and after the FDA put out a consumer advisory.

c. *Third*, the Abbott Formula Recall was anything but "voluntary." The cascading harms necessitated the Abbott Formula Recall. The Abbott Formula Recall was only "voluntary" in the sense that the FDA had not formally issued a recall nor had the DoJ yet entered into a Consent Decree with the Company (as discussed below, the latter would be forthcoming three months later).[51]

210. Abbott's statement continued to misrepresent the narrative. The statement did not mention of the FDA's for-cause inspection or the FDA. To the uninformed reader, it appeared as if Abbott's thorough and "routine" testing for cronobacter had found a minor issue and Abbott was going above and beyond any legal requirements out of an abundance of caution. Instead, the testing that found cronobacter was the result of the FDA's for-cause inspection, which itself was necessitated by the October 2021 Sturgis Whistleblower complaint and reports of infant illnesses.

211. Abbott continued to mislead the public by stating that "all finished infant formula powder products are tested for *Cronobacter*, *Salmonella*, and other pathogens, and they must test negative before the product is released."[52] This statement suggests that Abbott tests each and every finished can before releasing it. [redacted] These and other misleading statements are currently the subject of a securities fraud lawsuit filed against Abbott.

[51] 21 C.F.R. § 7.40(b) explains that: "Recall may be undertaken voluntarily and at any time by manufacturers and distributors, or at the request of the Food and Drug Administration. A request by the Food and Drug Administration that a firm recall a product ***is reserved for urgent situations***."

[52] Recall Notice, Abbott (Feb. 17, 2022), https://www.similacrecall.com/us/en/home.html#:~:text=2022%20%E2%80%93%20UPDATE%3A%20Abbott%20is%20voluntarily,17.

212. [redacted] The Board's lack of oversight therefore directly resulted in misleading statements that now form the basis of a securities fraud suit seeking to hold the Company liable for its misstatements to shareholders.

213. On February 28, 2022, Abbott expanded the Abbott Formula Recall to include an additional lot of Similac PM 60/40.[53] This expanded recall was necessary because on February 18, 2022, the FDA received a fourth cronobacter case report of a death potentially associated with Abbott's product.[54] Abbott's statement said "the action comes after learning of the death of an infant who tested positive for *Cronobacter sakazakii* and who we were informed had consumed Similac PM 60/40 from this lot."[55]

3. The Sturgis Shutdown

214. On February 15, 2022, Abbott Nutrition ceased production at Sturgis.[56]

215. The Sturgis Shutdown lasted until June 4, 2022 and the Facility was only reopened when Abbott was able to meet conditions imposed by the Consent Decree.

---

[53] *Id*.
[54] FDA, *Timeline of Infant Formula Related Activities*, https://www.fda.gov/media/158737/download.
[55] Recall Notice, Abbott (Feb. 17, 2022), https://www.similacrecall.com/us/en/home.html#:~:text=2022%20%E2%80%93%20UPDATE%3A%20Abbott%20is%20voluntarily,17.
[56] FDA, *Timeline of Infant Formula Related Activities*, https://www.fda.gov/media/158737/download.

4. The Board Belatedly Learned of the Abbott Formula Recall and the Sturgis Shutdown.

216. [redacted]

217. [redacted]

218. [redacted]

219. [redacted]

220. [redacted]

[redacted]

221. [redacted]

[redacted]

[redacted]

[redacted]

F. The Board Failed to Take Action Following The FDA's Finding That Sturgis Formula Was "Produced Under Unsanitary Conditions and May Be Contaminated with Cronobacter."

222. On March 18, 2022, the FDA issued a Form 483 Letter to Abbott, after the Abbott Formula Recall and the Sturgis Shutdown, which memorialized the critical findings from its January-March 2022 inspection. The Form 483 concluded that Abbott failed to establish process controls "designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment," and failed to "ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source."[57] "[T]he totality of evidence obtained during [its] inspection caused [the] FDA to conclude that infant formulas produced at [the Sturgis Facility] were produced under unsanitary conditions and may be contaminated with Cronobacter."

223. The Form 483 detailed a number of repeated failures at Sturgis:

a. *First*, the document confirmed the presence of cronobacter in "medium and high care areas of powdered infant formula production," the presence of cronobacter on eight occasions between September 25, 2019 and February 20, 2022, and the presence of cronobacter on twenty occasions from February 6-20, 2022. Additionally, and omitted from

[57] FDA, FORM 483 LETTER TO ABBOTT NUTRITION, STURGIS, MI 1, 4 (2022).

Abbott's February 17, 2022 statement that cronobacter was not found in finished products, the Form 483 noted the presence of cronobacter twice, in 2019 and 2020, in finished products and that Abbott "found evidence of *Cronobacter* … in [Abbott's] powdered infant formula production environment" and "in finished powdered infant formula products."[58]

b. *Second*, the FDA observed several instances of standing water at Sturgis, which it noted was a repeat offense from its September 2021 inspection.[59] Specifically, the FDA observed water [redacted], water around the floor drain near potassium hydroxide tanks, on the floor near the floor scrubber, and in the basement.[60] In total, there were 310 water events between January 1, 2020 and February 1, 2022.

c. *Third*, the FDA observed repeated deficiencies with water in dryers and dry out procedures, including that no one validated drying procedures to ensure complete drying.[61] The FDA also noted that the dryers had a history of "internal deterioration" dating to September 2018.[62] [redacted][63]

d. *Fourth*, the Form 483 also evidenced Abbott's inability to address the root cause of the cronobacter. The FDA noted that Abbott failed to determine the root causes of three complaints of cronobacter, including one fatality, and one complaint of salmonella newport.[64]

[58] *Id.* at 6.
[59] *Id.* at 4.
[60] *Id.*
[61] *Id.* at 5.
[62] *Id.*
[63] *Id.*
[64] *Id.* at 6.

e. *Fifth*, the FDA also found that, contrary to Abbott's policy, Abbott did not request that a sample be evaluated for microbial analysis after a report of cronobacter infection.[65] This revelation directly contradicts Abbott's statement on February 17, 2022 that it "retained samples related to the three complaints for *Cronobacter sakazakii* tested negative for *Cronobacter sakazakii*." In reality, Abbott failed to test retained samples for one baby who died when consuming its Similac Pro Total Comfort formula.[66]

224. The Board's information reporting system deficiencies were evidenced by its response to the FDA's findings. [redacted]

225. [redacted]

[65] *Id.* at 6-7.

[66] The Form 483 also detailed first-hand safety failures that the FDA witnessed—namely Sturgis employees failing to take proper precautions about transporting bacteria into the production area through their footwear. *Id.* at 7-8. It noted that contractors in January-February 2022 had failed to sanitize or change their shoes before entering the building, which was part of Abbott's "root cause analysis" for cronobacter at that time. *Id.* at 8.

G. The Board Failed To Meaningfully Oversee the Company's Response to The Abbott Formula Recall and Sturgis Shutdown.

226. [redacted] This failure to obtain timely information was a breach of the Board's fiduciary duties. [redacted]

1. [redacted]

227. [redacted] Of course, public news reports continued almost daily and the corporate trauma and fall out from Sturgis continued.

228. [redacted]:

a. On February 18, 2022, parents with sick children filed lawsuits against Abbott. *The Chicago Tribune* reported on the filings in a March 2, 2022 article titled "Abbott facing lawsuits, FDA investigation over recalled infant formula after reports of illness, death," which reported that at "least half a dozen of [] lawsuits have been filed in the U.S. District Court for the Northern District of Illinois, with filings on Feb. 25 and March 1, . . . alleg[ing] that north suburban-based Abbott failed to warn consumers about the risks of feeding the formula to their babies before they purchased it and that Abbott didn't promptly replace the recalled formulas." The article quoted an Abbott spokesperson again claiming that all infant formula must test

negative "before any product is released," which is misleading because not every lot of infant formula is tested before distribution. [redacted]

b. On February 24, 2022, the FDA informed Abbott of an additional infant who was sick from cronobacter. That infant subsequently passed away. [redacted]

c. On February 28, Abbott expanded its recall of formula following additional reports of an illness in a child. [redacted]

d. On March 18, 2022, the FDA completed its six-week long inspection of the Sturgis Facility and issued its findings to Abbott management. [redacted] A March 24, 2022 CNN article quotes an Abbott statement about the FDA findings noting that the Company "ha[d] already begun implementing corrective actions and enhancements at the facility," but [redacted]

e. On March 22, 2022, the FDA took the unusual step of publicly releasing redacted versions of the 2019, 2021, and 2022 Form 483 and Inspection Report findings for the Sturgis Facility. The contents of the documents were reported in a March 23, 2022 *Chicago Tribune* article. Among other things, the article reveals the FDA "report gives the agency's preliminary findings and ***is likely to be followed by a formal report and a warning to the***

company."

f. On April 20, 2021, during the Quarterly Earnings call, Abbott's CEO Ford continued to downplay Abbott's role in the infant deaths. He took the position—despite the widespread contamination of cronobacter at the Sturgis Facility, positive tests throughout the Facility, and positive tests in infants around the country—that Abbott's formula was not the source of contamination because "the FDA and CDC found that there is no genetic match between the strains of the bacteria identified in non-product contact areas of our facility and available samples obtained from customer complaints." However, the widespread cronobacter contamination throughout Sturgis indicates that there were multiple other strains of cronobacter, making Abbott's narrowing to a one-for-one genetic test improperly cramped.

g. On April 28, 2022, the Sturgis Whistleblower sent their FDA complaint to Congresswoman DeLauro, who submitted it into the record during an Agricultural Appropriations Subcommittee hearing. Congresswoman DeLauro concomitantly issued a press release describing the Sturgis Whistleblower's allegations as "extremely disturbing." The complaint was widely publicized. For example, *Politico* published an article the morning of April 28 ( ) titled "Whistleblower warned FDA about formula plant months before baby deaths."

229. Abbott management issued a statement, , the same day that cast aspersions on the Sturgis Whistleblower, describing their allegations as "evolving,

new and escalating allegations to multiple authorities." Abbott then described the complaint as a "new document" despite the fact that the complaint was sent to the FDA more than six months prior, in October 2021, and mirrored allegations made to OSHA in February 2021.

230. [redacted]

2. [redacted]

231. [redacted]

232. [redacted]

233. [redacted]

234. [redacted]

[redacted]

a. [redacted]

b. [redacted]

c. [redacted]

d. [redacted]

e. [redacted]

f. [redacted]

[redacted]

g. [redacted]

h. [redacted]

i. [redacted]

j. [redacted]

k. [redacted]

l. [redacted]

235. [redacted]

236. [redacted]

[redacted]

237. [redacted]

238. [redacted]

239. [redacted]

240. [redacted]

241. [redacted]

3. Abbott Entered Into A Civil Consent Decree with the DoJ Setting Forth Requirements to Re-Open Sturgis.

242. On May 16, 2022, the DoJ filed a complaint and a proposed consent decree that set forth specific measures designed to increase safety and ensure compliance with federal regulations governing infant formula that Abbott was required to take in order to resume manufacturing at the Sturgis Facility.[67]

243. The DoJ complaint alleged that Abbott and certain quality assurance and Sturgis management staff (including Randall, a Defendant in this action and in the Consent Decree) "manufactured powdered infant formula under conditions and using practices that failed to comply with regulations designed to ensure the quality and safety of infant formula, including protection against the risk of contamination from bacteria such as Cronobacter sakazakii."[68]

244. That same day, by joint motion, Abbott agreed to the proposed Consent Decree. Under the Consent Decree, which was entered by a federal court in Michigan the same day,[69] Abbott was required to retain an outside expert assistance to bring its facility into compliance with the FDCA and good manufacturing practice regulations in order to help mitigate the shortage of infant formula while also protecting public health. [70]

245. [redacted]

[67] Press Release, Dep't of Just., Justice Department Files Complaint and Proposed Consent Decree to Ensure Safety of Abbott Laboratories' Infant Formula (May 16, 2022), https://www.justice.gov/opa/pr/justice-department-files-complaint-and-proposed-consent-decree-ensure-safety-abbott.
[68] *Id.*
[69] Consent Decree for Permanent Injunction, *United States v. Abbott Labs.*, No. 1:22-cv-00441 (N.D. Ill. May 16, 2022), ECF No. 2-1.
[70] *Id.* at ¶ 8(A).

4. [redacted]

246. [redacted]

247. [redacted]

248. [redacted]

249. [redacted]

250. [redacted]

[redacted] As detailed above, nearly one month earlier, the DoJ filed a complaint and entered into a consent decree with Abbott. Its complaint for a permanent injunction contained harsh rebukes of Abbott's manufacturing processes, including that:

> Ongoing inadequacies in manufacturing conditions and practices at Defendants' facilities demonstrate that [Defendant[] Abbott, Keenan Gale, TJ Hathaway, and Lori Randall] have been unwilling or unable to implement sustainable corrective

> actions to ensure the safety and quality of food manufactured for infants, a consumer group particularly vulnerable to foodborne pathogens. Defendants' violations of the [FDCA] and the likelihood that violations will reoccur in the absence of court action demonstrate that injunctive relief is necessary.[71]

251. The Consent Decree detailed a number of steps that the Company needed to take before Sturgis could restart production. [redacted]

252. [redacted]

VI. ABBOTT'S DIRECTORS AND OFFICERS CONSCIOUSLY DISREGARDED RED FLAGS CONCERNING THE QUALITY AND SAFETY OF ABBOTT'S INFANT FORMULA.

253. Defendants knew of numerous instances of corporate misconduct in the form of red flags, yet nevertheless breached their fiduciary duties to address the corporate misconduct. This corporate misconduct occurred for years leading up to the Abbott Formula Recall and Sturgis Shutdown.

[71] DoJ Complaint, at ¶ 7.

254. Further, the Directors ignored numerous red flags that came out of the Abbott Formula Recall and Sturgis Shutdown itself.

A. September 2010: Abbott Recalled $100 Million Worth of Infant Formula After Discovering Beetles at Sturgis.

255. The Abbott Board was aware of the enterprise-level risks associated with its infant formula business at least as early as 2010.

256. In September 2010, Abbott recalled Similac infant formula after finding ***warehouse beetles*** in finished cans of the product at the Sturgis Facility. The Company said at the time that the recall could result in ***$100 million*** of lost revenue.

257. The presence of beetles in finished infant formula product (that is, ***product that is ready to be shipped to consumers***) suggests a system-wide compliance failure of the highest magnitude. Finding beetles in finished product means safety failures must have occurred at numerous steps during the manufacturing process. Pest control processes must have failed to allow beetles to enter the Facility at all. The "kill step" during manufacturing in which product is heated to kill any organisms, may also have failed, because the beetles persisted in the product. Contamination of a finished product also indicates that cross-contamination procedures failed to prevent contamination because if beetles were indeed killed during the "kill" step, they were then later reintroduced into the product at the end of the manufacturing line.

258. In 2010, Abbott (rather than the FDA) identified the beetles through an "internal quality review." The FDA did not issue a Warning Letter to Abbott.

259. Under the procedures established by the Public Policy Committee Charter, Abbott's Board would not have heard about the beetle infestation at Sturgis until the recall was announced, because the Charter requires only that the Board be made aware of FDA Warning Letters, and none was issued respecting the beetle infestation.

260. Defendants Alpern, Austin, Liddy, Novakovic, Osborn, Scott, Tilton, and White were on Abbott's Board at the time of the beetle infestation, and therefore were made aware of questionable manufacturing processes that could lead to contamination of its infant formula product.

261. Despite this knowledge, the Abbott Directors established a system that would deliberately not bring "internal quality reviews" to the Public Policy Committee's attention. Put differently, Abbott's Board learned in 2010 that internal quality reviews could flag significant safety issues that could cost the company nine figures in sales, yet did not change its system to ensure that it would hear about the next corporate catastrophe.

B. June 2021: [redacted]

262. [redacted]

263. In May 2021, the Shanghai State Administration of Market Regulation fined Abbott's Chinese subsidiary, Abbott Laboratories Trading (Shanghai) Co., Ltd., approximately $1.4 million after it detected vanilla, a forbidden substance in infant formula products.

264. The Chinese regulator concluded that the vanilla got into the batch because of "residues in [the] pipeline in the production of another batch of products."

265. This manufacturing failure raised larger issues about Abbott's ability to safely manufacture products without cross-contamination, and general hygiene around Abbott's formula manufacturing.

266. [redacted]

[redacted]

C. February-June 2022: The Board Failed to Respond to Numerous Red Flags Related to the Safety and Quality of Sturgis-Manufactured Formula.

267. Between February 17, 2022, when the Abbott Infant Formula was announced, [redacted] Abbott's Board consciously disregarded and failed to take action in response to at least five Sturgis-related red flags. These include: (1) the Abbott Formula Recall; (2) the Sturgis Shutdown; (3) the FDA's March 22, 2022 public release of FDA's Form 483s from 2019, 2021, and 2022; (4) the April 29, 2022 public release by Rep. DeLauro of the October 2021 Sturgis Whistleblower complaint; and (5) the May 16, 2022 Consent Decree.

1. The Board Took No Action to Oversee The Abbott Formula Recall and Sturgis Shutdown.

268. On February 17, 2022, it was widely reported in the news media that Abbott was instituting the Abbott Formula Recall, and shutting down the Sturgis Facility.

269. [redacted]

270. [redacted]

271. [redacted]

272. [redacted]

273. [redacted]

274. [redacted]

[redacted]

275. [redacted]

276. [redacted]

2. The Board Did Not Respond To the FDA's Findings At Sturgis.

277. On March 22, 2022, the FDA took the rare step of publicly releasing Abbott's 2019 and 2021 Form 483 findings, as well as the Form 483 finding for its just-concluded 2022 for-cause inspection. The revelations of prior cronobacter-positive tests at Sturgis, alongside information about the "egregiously unsanitary" conditions at Sturgis, prompted another round of press scrutiny against Abbott. The release of the FDA findings were widely reported in the press.

278. [redacted]

[redacted]

279. [redacted]

280. This passivity again violated the Director Defendants' fiduciary duties to properly oversee the Company's response to a red flag.

3. [redacted]

281. On April 28, 2022, Rep. DeLauro issued a press release and submitted the October 2021 Sturgis Whistleblower complaint into the record during a Congressional Subcommittee hearing. The submission prompted widespread media coverage, including the day it was released. As discussed above, [redacted]

282. [redacted]

283. [redacted]

4. [redacted]

284. On May 16, 2022, the DoJ filed its complaint for a permanent injunction against Abbott and three of its executives, Division Vice-President of Quality Assurance Lori J. Randall, Sturgis Director of Quality Keenan S. Gale, and Sturgis Site Director TJ Hathaway. As noted above, this statutory injunction under the FDCA resulted in Abbott simultaneously agreeing to a consent decree of permanent injunction.

285. [redacted]

286. [redacted]

287. [redacted]

288. [redacted]

5. [redacted]

289. On May 25, 2022, the House Energy and Commerce Committee's Subcommittee on Oversight and Investigations held a hearing on "Formula Safety and Supply: Protecting the Health of America's Babies." FDA Commissioner Robert M. Califf and Deputy Commissioner

Frank Yiannas both testified. During his testimony, Commissioner Califf called the conditions at Sturgis "egregiously unsanitary" and the FDA's inspection results "shocking." He told Congress that the Facility had bacteria contaminations in multiple locations, cracks in its equipment, leaks from its roof, standing water, and that Sturgis employees inadequately washed their hands.

290. Abbott's Calamari also testified. Calamari covered only the FDA's January-March 2022 inspection of the Sturgis Facility. Though his written testimony was limited in other ways and omitted key facts regarding conditions at the Sturgis Facility, Calamari admitted that Abbott's own testing during the inspection had found cronobacter at Sturgis, albeit in "non-product-contact areas." Indeed, he repeatedly sought to characterize the bacteria as found in "non-product-contact" (or "environmental") areas of the Facility, as opposed to in finished formula product. Notably, Calamari also affirmatively stated that finished product testing conducted by the FDA and Abbott between January and March 2022 had come back negative for cronobacter and salmonella.

291. Calamari's testimony misleadingly suggested that cronobacter had not been found in finished infant formula product at Sturgis (and, instead, in "environmental" or "non-product-areas"). In reality, Abbott's own testing had identified cronobacter ***three times*** in finished formula product that was ready for distribution to customers, in August 2019, September 2019, and again in June 2020. Not only was the bacteria found on separate occasions but also in different Sturgis production lines, suggesting the bacteria was widespread. The FDA identified the September 2019 and June 2020 positive tests in its Form 483 findings at the conclusion of the January-March 2022 inspection.[72]

[72] FDA, FORM 483 LETTER TO ABBOTT NUTRITION, STURGIS, MI 3 (2022).

292. Because the Board had an insufficient reporting system, and failed to act in response to the red flags of the Abbott Formula Recall and the Sturgis Shutdown, [redacted]

VII. THE DIRECTOR DEFENDANTS VIOLATED SECTION 14(A) OF THE EXCHANGE ACT AND SEC RULE 14a-9, AND BREACHED THEIR FIDUCIARY DUTIES, BY CAUSING THE COMPANY TO MAKE MATERIALLY MISLEADING STATEMENTS IN ITS PROXIES.

293. The Director Defendants violated Section 14(a) of the Exchange Act and SEC Rule 14a-9 by causing Abbott to issue proxy statements that did not disclose: (i) Abbott's failure to establish a proper information-reporting system relating to safety; (ii) Abbott's failure to properly respond to numerous red flags about unsafe conditions at the Sturgis Facility; (iii) Abbott's inadequate controls to safely manufacture powdered infant formula; (iv) Abbott's efforts to conceal evidence of contamination at the Sturgis Facility; and (v) Abbott's exposure to serious and significant regulatory and legal risks. The Director Defendants' failure to disclose those material facts likewise constitutes a breach of their fiduciary duties.

A. Numerous Director Defendants Caused Abbott to Issue the Materially False or Misleading 2020 Proxy Statement.

294. On March 13, 2020, Defendants Alpern, Austin, Blount, Ford, Kumbier, Liddy, McDew, McKinstry, Novakovic, Osborn, Starks, Stratton, Tilton, and White caused Abbott to file a Proxy Statement with the Securities and Exchange Commission on Form DEF 14A (the "2020 Proxy") in connection with the 2020 annual stockholders meeting scheduled for April 24, 2020.[73] In the 2020 Proxy Statement, these Defendants solicited stockholder votes to, among other things,

[73] Abbott, Proxy Statement (Form Def 14A) (2020).

(i) re-elect fourteen directors to the Board; and (ii) approve executive compensation. With respect to each of these solicited votes, these Defendants issued materially false or misleading statements.

295. With respect to Board re-elections, the 2020 Proxy stated that its current leadership structure, comprised of the Chairman of the Board and Chief Executive Officer, a Lead Independent Director, and independent chairs of its Audit, Compensation, Nominations and Governance, and Public Policy Committees, was in the "best interests of Abbott and its shareholders":

> The Board reviews its leadership structure on at least an annual basis. The Board has determined that this leadership structure ensures the appropriate level of oversight, independence and responsibility is applied to all Board decisions, including risk oversight, and is in the best interests of Abbott and its shareholders.[74]

Further, the 2020 Proxy Statement described the Board's process of identifying qualified individuals to be directors, as follows, in relevant part:

> The Nominations and Governance Committee assists the Board of Directors in identifying individuals qualified to become Board members and recommends to the Board the nominees for election as directors at the next annual meeting of shareholders. The process used by the Nominations and Governance Committee to identify a nominee to serve as a member of the Board of Directors depends on the qualities being sought. From time to time, Abbott engages an executive search firm to assist the Committee in identifying individuals qualified to be Board members.
>
> Abbott's outline of directorship qualifications, which is part of Abbott's corporate governance guidelines, is available in the corporate governance section of Abbott's investor relations website (www.abbottinvestor.com). These qualifications describe specific characteristics that the Nominations and Governance Committee and the Board take into consideration when selecting nominees for the Board, such as: strong management experience and senior-level experience in medicine, hospital administration, medical and scientific research and development, finance, international business, technology, government, and academic administration. An

[74] *Id.* at 20.

individual nominee is not required to satisfy all the characteristics listed in the outline of directorship qualifications and there is no requirement that all such characteristics be represented on the Board.

In addition, Board members should have backgrounds that, when combined, provide a portfolio of experience and knowledge that will serve Abbott's governance and strategic needs. Board candidates will be considered on the basis of a range of criteria, including broad-based business knowledge and relationships, prominence, and excellent reputations in their primary fields of endeavor, as well as a global business perspective and commitment to good corporate citizenship. Directors should have demonstrated experience and ability that is relevant to the Board of Directors' oversight role with respect to Abbott's business and affairs.

* * *

In the process of identifying nominees to serve as members of the Board of Directors, the Nominations and Governance Committee considers the Board's diversity of relevant experience, areas of expertise, ethnicity, gender, and geography and assesses the effectiveness of the process in achieving that diversity.

The process used to identify and select nominees has resulted in a balanced, diverse, and well-rounded Board of Directors that possesses the skills, experiences, and perspectives necessary for its oversight role. All of Abbott's directors exhibit:

✓ Global business perspective

✓ Successful track record

✓ Innovative thinking

✓ Knowledge of corporate governance requirements and practices

✓ High integrity

✓ ***Commitment to good corporate citizenship.*** [75]

[75] *Id.* at 21-22.

296. The 2020 Proxy also represented that Abbott is "***committed to strong corporate governance***" and that the Board oversees enterprise risks, as follows, in relevant part:

> CORPORATE GOVERNANCE
>
> ***Abbott is committed to strong corporate governance that is aligned with shareholder interests. Our Board spends significant time with the Company's senior management to understand the dynamics, issues, and opportunities for Abbott. During these interactions, directors provide insights and ask probing questions which guide management decision-making. This collaborative approach to risk oversight and emphasis on long term sustainability begins with our leaders and is engrained in the culture of our Company. The Board also regularly monitors leading practices in governance and adopts measures that it determines are in the best interest of Abbott and its shareholders***.[76]

297. The 2020 Proxy also described the Board's Public Policy Committee's role in assisting in Board oversight as follows, in relevant part:

> **Public Policy Committee**
>
> The Public Policy Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to:
>
> • Certain areas of ***legal and regulatory compliance, including evaluating Abbott's compliance policies and practices and reviewing Abbott's compliance program***,
>
> • ***Governmental affairs and healthcare compliance issues that affect Abbott***, and
>
> • Abbott's public policy, including evaluating Abbott's social responsibility policies and practices and reviewing social, political, economic, and environmental trends and public policy issues that affect or could affect Abbott's business activities, performance, and public image.[77]

298. Those statements conveyed that the Board (i) was comprised of members with sufficient relevant knowledge and experience to exercise proper risk oversight, including Abbott's

[76] *Id.* at 6.
[77] *Id.* at 26.

legal, regulatory and healthcare compliance; (ii) maintained sufficient systems and controls to oversee enterprise risk; and (iii) interacted meaningfully with Abbott's senior management and performed audits to confirm that risk assessment and mitigation practices were consistent with Abbott's business strategy.

299. The 2020 Proxy Statement omitted any disclosures regarding: (i) Abbott's failure to establish a proper information-reporting system relating to safety; (ii) Abbott's failure to properly respond to numerous red flags about unsafe conditions at the Sturgis Facility; (iii) Abbott's inadequate controls to safely manufacture powdered infant formula; (iv) Abbott's efforts to conceal evidence of contamination at the Sturgis Facility; and (v) Abbott's exposure to serious and significant regulatory and legal risks.

300. The 2020 Proxy Statement also omitted any disclosures reflecting or acknowledging that Defendants failed to address the unsafe practices and conditions at Sturgis.

301. The 2020 Proxy Statement harmed Abbott by interfering with the proper governance on its behalf that follows stockholders' informed voting of directors. As a result of the false or misleading statements in the 2020 Proxy Statement, Abbott stockholders voted to re-elect Defendants Alpern, Austin, Blount, Ford, Kumbier, Liddy, McDew, McKinstry, Novakovic, Osborn, Starks, Stratton, Tilton, and White to the Board.

302. The 2020 Proxy Statement also urged stockholders to approve an advisory resolution regarding compensation paid to named executives. In support of the requested approval, the 2020 Proxy Statement stated:

> ***Abbott and its Compensation Committee have designed a compensation program that balances short- and long-term objectives to focus our executives on actions that create value today, while building for sustainable future success.*** Approximately two-thirds of our pay is equity-based, directly tying

a significant portion of executive compensation to shareholder returns.

Our compensation program is market-based (to ensure our ability to attract and retain talented executives) and produces compensation outcomes that are performance-based (to incent the achievement of profitable growth that increases shareholder value).

* * *

COMPENSATION OUTCOMES ARE PERFORMANCE-BASED

Other than base salary, which is the smallest component of our executives' compensation, all remaining components of Total Direct Compensation (i.e., annual incentive, performance-based restricted stock awards, and stock options) are aligned with individual, business segment and Company performance.[78]

* * *

COMPENSATION PROGRAM IS DIRECTLY LINKED TO BUSINESS STRATEGY

Our compensation program is also linked directly to our business strategy, to ensure that officers are focused on those activities that drive our business strategy and create value for shareholders.

* * *

Officer financial goals are set and assessed based on adjusted measures that the Committee believes more accurately reflect the results of our ongoing operations. We make certain adjustments for specified items, whether favorable or unfavorable, that are unusual or unpredictable, such as cost reduction initiatives, restructuring programs, integration activities and other business acquisition-related costs, and the impact of significant tax changes. We also exclude intangible amortization expense to provide greater visibility on the results of operations excluding these costs, similar to how Abbott's management internally assesses performance.

The Committee believes these adjusted measures provide a more stable assessment of Abbott's core business and encourage decision-making that considers long-term value. They also align compensation goals with the financial guidance we communicate to investors, which is also based on adjusted measures.

[78] *Id.* at 33.

* * *

COMPENSATION LINK TO SUSTAINABILITY

Our leadership covenant includes commitments to multiple environmental, social and governance efforts. Examples include:

• A sustainable infrastructure to drive quality, environmental, health and safety performance

• Human capital management to ensure an inclusive culture and the fair and balanced treatment of our employees

• Quality products provided at competitive prices to patients and consumers at hospitals and retailers

• ***Abbott's Code of Conduct to ensure adequate internal controls for financial reporting and compliance with applicable laws and regulations***.[79]

303. Those statements conveyed that Abbott's compensation system encouraged executive actions that created value for shareholders and built "sustainable future success." In reality, Abbott's compensation system actually encouraged—and consistently rewarded—excessive risk-taking, turning a blind eye to the egregiously unsafe practices and conditions at the Sturgis Facility, and jeopardizing the continued supply of safe infant powdered formula to consumers, including vulnerable infants. The Director Defendants knew or should have known that they had breached their fiduciary duties to the Company and exposed the Company to significant and material risks and liability by failing to establish a system of board-level controls that would allow the Board to properly oversee the Company's infant formula business.

304. Under this misrepresentation, numerous Abbott stockholders voted in support of payouts of base salary and bonuses, as well as Long-Term Incentive awards ("LTI"), to each of the following Defendants: White ($4.4 million payout and $15.125 million in LTI), Ford ($1.56

[79] *Id.* at 36.

million payout and $6.95 million in LTI), and Salvadori ($799,400 payout and $4.7 million in LTI), as well as additional members of Abbott management, without the benefit of material information regarding these Defendants' continued and ongoing failure to oversee the Company's business risks, and their continued and ongoing failure to reform the Company's compensation structures so that they did not promote such improper and unlawful activity.

B. Numerous Director Defendants Caused Abbott to Issue the Materially False and Misleading 2021 Proxy Statement.

305. On March 12, 2021, Defendants Alpern, Austin, Blount, Ford, Kumbier, McDew, McKinstry, Osborn, Roman, Starks, Stratton, Tilton, and White caused Abbott to file a Proxy Statement with the Securities and Exchange Commission on Form DEF 14A (the "2021 Proxy") in connection with the 2021 annual stockholders meeting scheduled for April 23, 2021.[80] In the 2021 Proxy Statement, these Defendants solicited stockholder votes to, among other things, (i) elect and re-elect thirteen individuals to the Board; (ii) approve executive compensation; and (iii) decide whether to adopt a policy requiring an independent Chairman. With respect to each of these solicited votes, these Defendants issued materially false or misleading statements.

306. With respect to Board elections, the 2021 Proxy assured that its current leadership structure, comprised of the Chairman of the Board and Chief Executive Officer, a Lead Independent Director, and independent chairs of its Audit, Compensation, Nominations and Governance, and Public Policy Committees, was in the "best interests of Abbott and its shareholders":

> The Board reviews its leadership structure on at least an annual basis. The Board has determined that this leadership structure ensures the appropriate level of oversight, independence and responsibility is applied to all Board decisions, including risk

[80] Abbott, Proxy Statement (Form Def 14A) (2021).

> oversight, and is in the best interests of Abbott and its shareholders.[81]

307. Further, the 2021 Proxy Statement described the Board's process of identifying qualified individuals to be directors, as follows, in relevant part:

> The Nominations and Governance Committee assists the Board of Directors in identifying individuals qualified to become Board members and recommends to the Board the nominees for election as directors at the next annual meeting of shareholders. The process used by the Nominations and Governance Committee to identify a nominee to serve as a member of the Board of Directors depends on the qualities being sought. From time to time, Abbott engages an executive search firm to assist the Committee in identifying individuals qualified to be Board members. Mr. Roman was recommended as a director nominee by a third-party search firm retained to help identify and evaluate potential director nominees.
>
> Abbott's outline of directorship qualifications, which is part of Abbott's corporate governance guidelines, is available in the corporate governance section of Abbott's investor relations website (www.abbottinvestor.com). These qualifications describe specific characteristics that the Nominations and Governance Committee and the Board take into consideration when selecting nominees for the Board, such as: strong management experience and senior-level experience in medicine, hospital administration, medical and scientific research and development, finance, international business, technology, government, and academic administration. An individual nominee is not required to satisfy all the characteristics listed in the outline of directorship qualifications and there is no requirement that all such characteristics be represented on the Board.
>
> In addition, Board members should have backgrounds that, when combined, provide a portfolio of experience and knowledge that will serve Abbott's governance and strategic needs. Board candidates will be considered on the basis of a range of criteria, including broad-based business knowledge and relationships, prominence, and excellent reputations in their primary fields of endeavor, as well as a global business perspective and commitment to good corporate citizenship. Directors should have demonstrated experience and ability that is relevant to the Board of Directors' oversight role with respect to Abbott's business and affairs. Each director's biography

[81] *Id.* at 23.

includes the particular experience and qualifications that led the Board to conclude that the director should serve on the Board.[82]

* * *

In the process of identifying nominees to serve as members of the Board of Directors, the Nominations and Governance Committee considers the Board's diversity of relevant experience, areas of expertise, ethnicity, gender, and geography and assesses the effectiveness of the process in achieving that diversity.

The process used to identify and select nominees has resulted in a balanced, diverse, and well-rounded Board of Directors that possesses the skills, experiences, and perspectives necessary for its oversight role. All of Abbott's directors exhibit:

✓ Global business perspective

✓ Successful track record

✓ Innovative thinking

✓ Knowledge of corporate governance requirements and practices

✓ High integrity

✓ ***Commitment to good corporate citizenship***[83]

* * *

The Nominations and Governance Committee assists the Board of Directors in identifying individuals qualified to become Board members and recommends to the Board the nominees for election as directors at the next annual meeting of shareholders. The process used by the Nominations and Governance Committee to identify a nominee to serve as a member of the Board of Directors depends on the qualities being sought. From time to time, Abbott engages an executive search firm to assist the Committee in identifying individuals qualified to be Board members. Mr. Roman was recommended as a director nominee by a third-party search firm retained to help identify and evaluate potential director nominees.

Abbott's outline of directorship qualifications, which is part of Abbott's corporate governance guidelines, is available in the

[82] *Id.* at 24.
[83] *Id.* at 25.

> corporate governance section of Abbott's investor relations website (www.abbottinvestor.com). These qualifications describe specific characteristics that the Nominations and Governance Committee and the Board take into consideration when selecting nominees for the Board, such as: strong management experience and senior-level experience in medicine, hospital administration, medical and scientific research and development, finance, international business, technology, government, and academic administration. An individual nominee is not required to satisfy all the characteristics listed in the outline of directorship qualifications an academic administration. An individual nominee is not required to satisfy all the characteristics listed in the outline of directorship qualifications and there is no requirement that all such characteristics be represented on the Board.
>
> ***In addition, Board members should have backgrounds that, when combined, provide a portfolio of experience and knowledge that will serve Abbott's governance and strategic needs.*** *Board candidates will be considered on the basis of a range of criteria, including broad-based business knowledge and relationships, prominence, and excellent reputations in their primary fields of endeavor, as well as a global business perspective and commitment to good corporate citizenship.* ***Directors should have demonstrated experience and ability that is relevant to the Board of Directors' oversight role with respect to Abbott's business and affairs. Each director's biography includes the particular experience and qualifications that led the Board to conclude that the director should serve on the Board.***[84]

308. The 2021 Proxy also represented that Abbott is "committed to strong corporate governance" and that the Board oversees enterprise risks, as follows, in relevant part:

> CORPORATE GOVERNANCE
>
> ***Abbott is committed to strong corporate governance that is aligned with shareholder interests. Our Board spends significant time with Abbott's senior management to understand global dynamics, challenges, and opportunities for Abbott. During these interactions, directors provide insights and ask probing questions which guide management decision making. This collaborative approach to risk oversight and emphasis on long-term***

[84] *Id.* at 24.

sustainability begins with our leaders and is engrained in Abbott's culture.[85]

* * *

Each year, Abbott's directors evaluate the effectiveness of the Board and its Committees in performing its governance and risk oversight responsibilities. Directors assess the performance of their peers, as well as the full Board of Directors and each of the Committees on which they serve[.][86]

Audit Committee

The Audit Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to:

• Abbott's accounting and financial reporting practices and the audit process,

• The quality and integrity of Abbott's financial statements,

• The independent auditors' qualifications, independence, and performance,

• The performance of Abbott's internal audit function and internal auditors,

• Legal and regulatory compliance relating to financial matters, including accounting, auditing, financial reporting, and securities law issues, and

• Enterprise risk management, including major financial and cybersecurity risk exposures.

In performing these functions, the Audit Committee meets regularly with the independent auditor, Abbott's management, and Abbott's internal auditors to review the adequacy, effectiveness and quality of Abbott's accounting and financial reporting principles, policies, procedures and controls, as well as Abbott's enterprise risk management, including Abbott's risk assessment and risk management policies.[87]

[85] *Id.* at 8.
[86] *Id.* at 26.
[87] *Id.* at 27-28.

309. The 2021 Proxy also described the Board's Public Policy Committee's role in assisting in Board oversight as follows, in relevant part:

> PUBLIC POLICY COMMITTEE
>
> The Public Policy Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to:
>
> • ***Certain areas of legal and regulatory compliance, including evaluating Abbott's compliance policies and practices and reviewing Abbott's compliance program,***
>
> • ***Governmental affairs and healthcare compliance issues that affect Abbott,*** and
>
> • Abbott's public policy, including evaluating Abbott's social responsibility policies and practices and reviewing social, political, economic, and environmental trends and public policy issues that affect or could affect Abbott's business activities, performance, and public image.[88]

310. Those statements conveyed that the Board (i) was comprised of members with sufficient relevant knowledge and experience to exercise proper risk oversight, including Abbott's legal, regulatory and healthcare compliance; (ii) maintained sufficient systems and controls to oversee enterprise risk; and (iii) interacted meaningfully with Abbott's senior management and performed audits to confirm that risk assessment and mitigation practices were consistent with Abbott's business strategy.

311. The 2021 Proxy Statement omitted any disclosures regarding: (i) Abbott's failure to establish a proper information-reporting system relating to safety; (ii) Abbott's failure to properly respond to numerous red flags about unsafe conditions at the Sturgis Facility; (iii) Abbott's inadequate controls to safely manufacture powdered infant formula; (iv) Abbott's efforts

[88] *Id.* at 29.

to conceal evidence of contamination at the Sturgis Facility; and (v) Abbott's exposure to serious and significant regulatory and legal risks.

312. The 2021 Proxy Statement also omitted any disclosures reflecting or acknowledging that Defendants failed to address the unsafe practices and conditions at Sturgis, even after the Sturgis Whistleblower submitted their complaint to OSHA in February 2021.

313. The 2021 Proxy Statement harmed Abbott by interfering with the proper governance on its behalf that follows stockholders' informed voting of directors. As a result of the false or misleading statements in the 2021 Proxy Statement, Abbott stockholders voted to elect and re-elect Defendants Alpern, Austin, Blount, Ford, Kumbier, McDew, McKinstry, Osborn, Roman, Starks, Stratton, Tilton, and White to the Board.

314. The 2021 Proxy Statement also urged stockholders to approve an advisory resolution regarding compensation paid to named executives. In support of the requested approval, the 2021 Proxy Statement stated:

> Abbott and its Compensation Committee have designed a compensation program that balances short- and long-term objectives to focus our executives on actions that create value today, while building for sustainable future success. Approximately two-thirds of our pay is equity-based, directly tying a significant portion of executive compensation to shareholder returns.
>
> Our compensation program is market-based (to ensure our ability to attract and retain talented executives) and produces compensation outcomes that are performance-based (to incent the achievement of profitable growth that increases shareholder value).[89]

315. With respect to Abbott's Annual Incentive Plan, the 2021 Proxy stated that Abbott rewarded its each business leader based, in part, on their "extraordinary response to the pandemic," including "Global Manufacturing ramp up to meet demand" and "business

[89] *Id.* at 35.

continuity" and "a focus on supply chain management that ensured customer needs were met," as follows, in relevant part:

> The goals used to determine annual incentive payouts for Abbott executive officers were set at the beginning of 2020. Abbott did not adjust 2020 financial goals due to the impact of the pandemic. Instead, ***the Compensation Committee evaluated and rewarded each business leader based on their original goals, as well as their contribution to the Company's extraordinary response to the pandemic***.

This response, which enhanced Abbott's position as a world leader in diagnostic testing, included:

> • The timely development of multiple COVID-19 related diagnostic tests across Abbott's broad diagnostics portfolio.
>
> • Global manufacturing ramp up to meet demand, with expansions at existing facilities and the creation of two new manufacturing sites in the U.S.
>
> In addition, business continuity across the Company was maintained through close partnerships with existing suppliers and a focus on supply chain management that ensured customer needs were met and R&D programs continued yielding approvals and a strong pipeline for future growth.[90]

316. The 2021 Proxy also stated that Abbott's Compensation Program is linked to its business strategy and sustainability, as follows, in relevant part:

> COMPENSATION PROGRAM IS DIRECTLY LINKED TO BUSINESS STRATEGY
>
> Our compensation program is also linked directly to our business strategy, to ensure that officers are focused on those activities that drive our business strategy and create value for shareholders.
>
> * * *
>
> Officer financial goals are set and assessed based on adjusted measures that the Committee believes more accurately reflect the results of our ongoing operations. We make certain adjustments for

[90] *Id.* at 36.

> specified items, whether favorable or unfavorable, that are unusual or unpredictable, such as cost reduction initiatives, restructuring programs, integration activities and other business acquisition-related costs, and the impact of significant tax changes. We also exclude intangible amortization expense to provide greater visibility on the results of operations excluding these costs, similar to how Abbott's management internally assesses performance.
>
> The Committee believes these adjusted measures provide a more stable assessment of Abbott's core business and encourage decision-making that considers long-term value. They also align compensation goals with the financial guidance we communicate to investors, which is also based on adjusted measures.
>
> COMPENSATION LINK TO SUSTAINABILITY
>
> Our leadership covenant includes commitments to multiple environmental, social and governance efforts. Examples include:
>
> • ***A sustainable infrastructure to drive quality, environmental, health and safety performance***
>
> • Human capital management to ensure an inclusive culture and the fair and balanced treatment of our employees
>
> • ***Quality products provided at competitive prices to patients and consumers at hospitals and retailers***
>
> • ***Abbott's Code of Conduct to ensure adequate internal controls for financial reporting and compliance with applicable laws and regulations.***[91]

317. Those statements conveyed that Abbott's compensation system encouraged executive actions that created value for shareholders and built "sustainable future success." In reality, Abbott's compensation system actually encouraged—and consistently rewarded—excessive risk-taking, turning a blind eye to the egregiously unsafe practices and conditions at the Sturgis Facility, and jeopardizing the continued supply of safe infant powdered formula to consumers, including vulnerable infants. The Director Defendants knew or should have known that they had breached their fiduciary duties to the Company and exposed the Company to

[91] *Id.* at 40.

significant and material risks and liability by failing to establish a system of board-level controls that would allow the Board to properly oversee the Company's infant formula business.

318. Under this misrepresentation, numerous Abbott stockholders voted in support of payouts of base salary and bonuses, as well as LTI, to each of the following Defendants: Ford ($3.675 million payout and $11.25 million in LTI); Funck ($1.28 million payout and $4.43 million in LTI); Salvadori ($905,000 payout and $3.804 million in LTI), and White ($1.9 million payout and $12 million in LTI) as well as additional members of Abbott management, without the benefit of material information regarding these Defendants' continued and ongoing failure to oversee the Company's business risks, and their continued and ongoing failure to reform the Company's compensation structures so that they did not promote such improper and unlawful activity.

319. The 2021 Proxy Statement also contained a stockholder proposal to adopt a policy to require an independent Chairman. The Board recommended voting against this proposal for the following reasons:

> As stated in Abbott's governance guidelines, "[t]he board of directors believes that it is important to retain the flexibility to allocate the responsibilities of the offices of chairman of the board and chief executive officer in any manner that it determines to be in the best interests of Abbott."[] The need for that flexibility has never been more apparent than this past year, when Abbott transitioned to a new CEO. The Board's current guidelines provided the Board with the flexibility necessary to adopt the leadership structure in the best interests of Abbott and its shareholders during this transition.
>
> Indeed, ***every year, the Board reviews its leadership structure to ensure the appropriate level of oversight, independence, and responsibility. The Board continues to believe that flexibility coupled with a strong Lead Independent Director is best for Abbott and its shareholders.*** Abbott's Lead Independent Director is selected from among the ranks of independent directors. In that role, the Lead Independent Director consults directly with major shareholders on Abbott business. The Lead Independent Director oversees the Board evaluation process. The Lead Independent

> Director is empowered to call meetings of the independent directors, if necessary. And the Lead Independent Director can review and approve agenda items, the Board's schedule, and, where appropriate, information provided to other Board members.[92]

320. The statements conveyed that Abbott's corporate governance structure enabled the Board to oversee the management of the company and maximize return to shareholders and was "in the best interests" of the Company and Abbott shareholders. In reality, Abbott's board structure allowed senior executives and the Board to forsake their oversight responsibilities and accountability to the Company and its shareholders and, instead, enabled ongoing, unsafe operations of the Sturgis Facility and the manufacture and distribution of infant powdered formula products that failed to meet FDA quality and safety standards.

321. The 2021 Proxy Statement, which contained materially misleading statements and deprived shareholders of adequate information necessary to make a reasonably informed decision, caused Abbott's stockholders to vote against the proposal to require an independent chairman.

C. Numerous Director Defendants Caused Abbott to Issue the Materially False and Misleading 2022 Proxy Statement.

322. On March 18, 2022, Defendants Alpern, Blount, Ford, Gonzalez, Kumbier, McDew, McKinstry, Osborn, Roman, Starks, Stratton, and Tilton caused Abbott to file a Proxy Statement with the Securities and Exchange Commission on Form DEF 14A (the "2022 Proxy") in connection with the 2022 annual stockholders meeting scheduled for April 29, 2022.[93] In the 2022 Proxy Statement, these Defendants solicited stockholder votes to, among other things, (i) re-elect twelve directors to the Board; (ii) approve executive compensation; and (iii) decide whether to adopt a policy requiring an independent Chairman. With respect to each of these solicited votes, these Defendants issued materially false or misleading statements.

[92] *Id.* at 96.
[93] Abbott Labs., Proxy Statement (Form Def 14A) (2022)

323. With respect to Board re-elections, the 2022 Proxy assured that its current leadership structure, comprised of the Chairman of the Board and Chief Executive Officer, a Lead Independent Director, and independent chairs of its Audit, Compensation, Nominations and Governance, and Public Policy Committees, was in the "best interests of Abbott and its shareholders":

> The Board reviews its leadership structure at least annually and has determined that this structure is in the best interests of Abbott and its shareholders at this time. This structure balances strong, independent oversight with extensive business knowledge and experience. The Board also retains the flexibility necessary to adopt the leadership structure in the best interests of Abbott and its shareholders based on the specific circumstances and needs of the business over time.[94]

324. Further, the 2022 Proxy Statement described the Board's process of identifying qualified individuals to be directors, as follows, in relevant part:

> In the process of identifying nominees to serve as members of the Board of Directors, the Nominations and Governance Committee considers the Board's diversity of relevant experience, areas of expertise, ethnicity, gender, and geography and assesses the effectiveness of the process in achieving that diversity.
>
> ***The process used to identify and select nominees has resulted in a balanced, diverse, and well-rounded Board of Directors that possesses the skills, experiences, and perspectives necessary for its oversight role. All of Abbott's directors exhibit***:
>
> ✓ Global business perspective
>
> ✓ Successful track record
>
> ✓ Innovative thinking
>
> ✓ ***Knowledge of corporate governance requirements and practices***
>
> ✓ High integrity

[94] *Id.* at 17.

✓ ***Commitment to good corporate citizenship***[95]

* * *

The Nominations and Governance Committee assists the Board of Directors in identifying individuals qualified to become Board members and recommends to the Board the nominees for election as directors at the next annual meeting of shareholders. The process used by the Nominations and Governance Committee to identify a nominee to serve as a member of the Board of Directors depends on the qualities being sought. From time to time, Abbott engages an executive search firm to assist the Committee in identifying individuals qualified to be Board members.

Abbott's outline of directorship qualifications, which is part of Abbott's corporate governance guidelines**,** is available in the corporate governance section of Abbott's investor relations website (www.abbottinvestor.com). These qualifications describe specific characteristics that the Nominations and Governance Committee and the Board take into consideration when selecting nominees for the Board, such as:

- strong management experience and senior level experience in medicine,
- hospital administration,
- medical and scientific research and development,
- finance,
- international business,
- technology,
- government, and
- academic administration.

An individual nominee is not required to satisfy all the characteristics listed in the outline of directorship qualifications and there is no requirement that all such characteristics be represented on the Board.

[95] *Id.* at 18.

> In addition, Board members should have backgrounds that, when combined, provide a portfolio of experience and knowledge that will serve Abbott's governance and strategic needs. Board candidates will be considered on the basis of a range of criteria, including broad based business knowledge and relationships, prominence, and excellent reputations in their primary fields of endeavor, as well as a global business perspective and commitment to good corporate citizenship. ***Directors should have demonstrated experience and ability that is relevant to the Board of Directors' oversight role with respect to Abbott's business and affairs.***[96]

325. The 2022 Proxy also represented that Abbott is "committed to strong governance" and that the Board oversees enterprise risks, as follows, in relevant part:

> BOARD OVERSIGHT
>
> Abbott is committed to strong governance that is aligned with shareholder interests. Our Board spends significant time with Abbott's senior management to understand global dynamics, challenges, and opportunities for Abbott. During these interactions, directors provide insights and ask probing questions which guide management decision making. This collaborative approach to risk oversight and emphasis on long-term sustainability begins with our leaders and is engrained in Abbott's culture.
>
> OVERSIGHT OF RISK
>
> The Board has risk oversight responsibility for Abbott, which it administers directly and with assistance from its Committees. Throughout the year, the Board and its Committees engage with management to discuss a wide range of enterprise risks, such as risks related to Abbott's businesses, enterprise and product cybersecurity, litigation, and human capital management, and they confirm the alignment of risk assessment and mitigation with business strategy. The Audit Committee conducts an annual review of the enterprise risk management process, including the program structure, risk assessment, and risk mitigation. The Board and its Committees also consult with advisors, including legal counsel, internal and external auditors, and consultants. Such engagement and consultations are done by the full Board, independent directors in executive sessions, or fully independent Committees, as appropriate.[97]

[96] *Id.* at 19.
[97] *Id.* at 20.

326. The 2022 Proxy also described the Board's Public Policy Committee's role in assisting in Board oversight as follows, in relevant part:

> PUBLIC POLICY COMMITTEE
>
> The Public Policy Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to:
>
> - ***Legal, regulatory, and healthcare compliance matters, including evaluating Abbott's compliance policies and practices and reviewing Abbott's compliance program,***
> - Product quality and cybersecurity matters,
> - Governmental affairs and political participation, including advocacy priorities, political contributions, lobbying activities, and trade association memberships,
> - Sustainability and social responsibility policies and practices, and
> - Social, political, economic, and environmental trends and public policy issues that affect or could affect Abbott's business activities, performance, and public image.[98]

327. Those statements conveyed that the Board (i) was comprised of members with sufficient relevant knowledge and experience to exercise proper risk oversight, including Abbott's legal, regulatory and healthcare compliance; (ii) maintained sufficient systems and controls to oversee enterprise risk; and (iii) interacted meaningfully with Abbott's senior management and performed audits to confirm that risk assessment and mitigation practices were consistent with Abbott's business strategy.

328. The 2022 Proxy Statement omitted any disclosures regarding: (i) Abbott's failure to establish a proper information-reporting system relating to safety; (ii) Abbott's failure to properly respond to numerous red flags about unsafe conditions at the Sturgis Facility; (iii)

[98] *Id.* at 23.

Abbott's inadequate controls to safely manufacture powdered infant formula; (iv) Abbott's efforts to conceal evidence of contamination at the Sturgis Facility; and (v) Abbott's exposure to serious and significant regulatory and legal risks.

329. The 2022 Proxy Statement also omitted any disclosures reflecting or acknowledging that Defendants failed to address the unsafe practices and conditions at Sturgis, even after the Sturgis Whistleblower submitted their complaint to OSHA in February 2021 and to the FDA in October 2021.

330. The 2022 Proxy Statement harmed Abbott by interfering with the proper governance on its behalf that follows stockholders' informed voting of directors. As a result of the false or misleading statements in the 2022 Proxy Statement, Abbott stockholders voted to re-elect Defendants Alpern, Blount, Ford, Gonzalez, Kumbier, McDew, McKinstry, Osborn, Roman, Starks, Stratton, and Tilton to the Board.

331. The 2022 Proxy Statement also urged stockholders to approve an advisory resolution regarding compensation paid to named executives. In support of the requested approval, the 2022 Proxy Statement stated:

> ***Abbott and its Compensation Committee have designed a compensation program that balances short- and long-term objectives to focus our executives on actions that create value today, while building for sustainable future success***. Approximately 90% of our pay is performance-based, directly tying a significant portion of executive compensation to Company performance and shareholder returns.
>
> Our compensation program is market-based (to ensure our ability to attract and retain talented executives) and produces compensation outcomes that are performance-based (to incent the achievement of profitable growth that increases shareholder value).
>
> * * *
>
> COMPENSATION OUTCOMES ARE PERFORMANCE-BASED

Other than base salary, which is the smallest component of our executives' compensation, all remaining components of Total Direct Compensation (i.e., annual incentive, performance-based restricted stock awards, and stock options) are aligned with individual, business segment and Company performance.[99]

* * *

COMPENSATION PROGRAM IS DIRECTLY LINKED TO BUSINESS STRATEGY

Our compensation program is also linked directly to our business strategy, to ensure that officers are focused on those activities that drive our business strategy and create value for shareholders.[100]

* * *

COMPENSATION LINK TO SUSTAINABILITY

Our leadership covenant is considered the minimum requirement of being an officer at Abbott. Any officer that does not fulfill the covenant can receive a reduction of up to 100% of their annual incentive and/or long-term incentive awards. In addition, our leadership covenant specifically states that senior leaders are accountable for the achievement of Abbott's 2030 Sustainability Plan goals.

The sustainability plan is integrated into our business plans, financial planning processes and existing governance structures. Each senior manager is responsible for taking actions in their organization that help achieve our targeted priority goals regarding:

Making access and affordability core to new product innovation

* * *

Creating a resilient, diverse and responsible supply chain

The COVID-19 pandemic tested the resilience of our supply chain to the extreme. Working across our business functions, we rose to the challenge by building an inventory of raw materials and products to support continuity of supply, monitoring performance more tightly to identify distressed suppliers early enough to implement contingency plans, mapping supplier manufacturing sites in known COVID-19 "hot spots" or in locations affected by government

[99] *Id.*
[100] *Id.* at 36.

> lockdowns, and offering COVID-19 testing for employees at a few strategic suppliers to ensure continued operations and supply.[101]

332. Those statements conveyed that Abbott's compensation system encouraged executive actions that created value for shareholders and built "sustainable future success." In reality, Abbott's compensation system actually encouraged—and consistently rewarded—excessive risk-taking, turning a blind eye to the egregiously unsafe practices and conditions at the Sturgis Facility, and jeopardizing the continued supply of safe infant powdered formula to consumers, including vulnerable infants. The Director Defendants knew or should have known that they had breached their fiduciary duties to the Company and exposed the Company to significant and material risks and liability by failing to establish a system of board-level controls that would allow the Board to properly oversee the Company's infant formula business.

333. Under this false impression, numerous Abbott stockholders voted in support of payouts of base salary and bonuses, as well as LTI, to each of the following Defendants: Ford ($3.168 million payout and $17.38 million in LTI); Funck ($1.05 million payout and $6 million in LTI); Salvadori ($925,700 payout and $4.78 million in LTI), and White ($1.9 million and $11 million in LTI), as well as other Abbott executives, without the benefit of material information regarding these Defendants' continued and ongoing failure to address the egregiously unsafe conditions and manufacturing practices at Sturgis and the control deficiencies at the Company, and their continued and ongoing failure to reform the Company's compensation structures so that they did not promote such improper and unlawful activity.

334. The 2022 Proxy Statement also contained a stockholder proposal to adopt a policy to require an independent Chairman. The Board recommended voting against this proposal for the following reasons:

---

[101] *Id.* at 37.

> Abbott's Board believes that ***the Board is in the best position to determine its structure in light of circumstances at a given moment and mindful of its obligations to shareholders to effectively oversee the management of the company and maximize return to shareholders***.
>
> Abbott's Board consists of former and current leaders from business, medicine, academics, and public service who combined have decades of corporate board and other experience and are capable to oversee the management of the company. At present, the Board believes that the current structure is in the best interests of Abbott and its shareholders, as it provides cohesive leadership and direction for the Board and executive management, as well as clear accountability and unified leadership in the execution of strategic initiatives and business plans. Still, the leadership of the Chair is balanced by a fully independent board which is organized in a manner that has and will lead to effective oversight.
>
> **Abbott's current board structure and corporate governance practices provide strong independent oversight of a combined Chair and CEO**.[102]

335. The 2022 Proxy Statement stated with respect Abbott's Board leadership as follows, in relevant part:

> Abbott shareholders are best served by preserving the Board's flexibility to determine the appropriate leadership structure for the Company.
>
> The Board regularly and carefully considers the merits of separating or combining the Chair and CEO positions, including whether an independent director should be chair. The Board believes that it is important to retain the flexibility to allocate the responsibilities of the offices of the Chair and CEO in the manner that it determines to be in the best interests of Abbott and its shareholders. Adopting a singular approach without the flexibility to adapt to company-specific circumstances would compromise the Board's ability to assess and implement the optimal oversight framework.[103]

336. The statements conveyed that Abbott's corporate governance structure enabled the Board to oversee the management of the company and maximize return to shareholders and was

[102] *Id.* at 76.
[103] *Id.* at 77.

"in the best interests" of the Company and Abbott shareholders. In reality, Abbott's board structure allowed senior executives and the Board to forsake their oversight responsibilities and accountability to the Company and its shareholders and, instead, enabled ongoing, unsafe operations of the Sturgis Facility and the manufacture and distribution of infant powdered formula products that failed to meet FDA quality and safety standards.

337. The 2022 Proxy Statement, which contained materially misleading statements and deprived shareholders of adequate information necessary to make a reasonably informed decision, caused Abbott's stockholders to vote against the proposal to require an independent chairman.

VIII. THE COSTS AND LIABILITIES INCURRED BY ABBOTT

338. In the wake of the Abbott Formula Recall and Sturgis Shutdown, Abbott suffered significant damage to its profitability, credibility, reputation, and business prospects. It also became exposed to substantial liability in regulatory and private actions.

339. For the first six months of 2022, Abbott reported a $393 million revenue decline year-over-year in U.S. pediatric nutritional sales due to the Abbott Formula Recall and Sturgis Shutdown. By the fourth quarter of 2022, sales were down more than 20%.

340. Abbott had costs associated with improvements to the Sturgis Facility to comply with the Consent Decree, and faces potential civil fines of $30,000 per day, up to $5 million per year, for violations of the Consent Decree.

341. Abbott lost significant market share during the Abbott Formula Recall and Sturgis Shutdown as competitors increased their infant formula output to help ease the national formula shortage crisis. Mead Johnson gained a market share of 60%, up from 35% before the Abbott Formula Recall, and Nestle Gerber also increased its output by approximately 50% in March and April 2022. By early May 2022, these efforts helped measurably boost national formula sales by volume and unit compared to the weeks prior to the Abbott Formula Recall.

342. Abbott also incurred additional costs to support "market share recovery," including the cost of providing rebates to WIC recipients during the infant formula shortage so that they could purchase competing products in states in which Abbott holds the WIC contract, costs to fund "brand recovery" efforts, and airfreight costs to fly in formula from Abbott's Ireland and Spain facilities. Abbott also established a $5 million independently administered fund "to help families who rely on [its] specialty formula EleCare with medical and living expenses as they weather this storm." Despite Abbott being a major producer of specialty formula, the FDA would later discover that Abbott "lacked a contingency plan to produce its lines of specialty metabolic and amino acid formulas that serve as a sole source of nutrition for thousands of infants with metabolic disorders."

343. Abbott also suffered significant loss in its market capitalization, as the price of its stock plummeted following revelations about the safety and compliance failures at its Sturgis Facility. Between February 17, 2022, the day the Abbott Formula Recall was announced, and June 8, 2022, when investors learned that Abbott was aware of the Sturgis Whistleblower's complaint months earlier than previously reported, Abbott's stock price declined $7.87, or 6.5%, for a total market capitalization loss of more than $13.88 billion. Abbott's stock price continued to decline in response to additional subsequent revelations and events relating to the unsafe conditions and repeated regulatory violations at its Sturgis Facility.

344. The revelations of safety and compliance failures at Sturgis have subjected Abbott to extensive government and regulatory scrutiny and litigation, including Congressional investigations, ongoing regulatory oversight and investigations of the Company by the SEC, the DoJ, and the FTC, and more than a dozen lawsuits brought against Abbott by parents whose infants consumed Abbott's recalled infant formula, consolidated as *In re Recalled Abbott*

Laboratories et al. Infant Formula Products Liab. Litig., Case No. 22-cv-2148, MDL No. 3037 (N.D. Ill.).

345. On January 20, 2023, the DoJ announced it was engaged in a criminal investigation of Abbott arising from the Abbott Formula Recall and Sturgis Shutdown. According to Abbott's securities filings, the DoJ launched the criminal investigation in November 2022. The DoJ's criminal investigation remains ongoing.

346. In its Form 10-Q for the period ending March 31, 2023, Abbott estimated "the range of possible loss for its legal proceedings and environmental exposures to be from approximately $25 to 35 million. Abbott also disclosed that the booked accrual balance at March 31, 2023 for those proceedings and exposures was approximately $30 million.

IX. DEMAND ON THE BOARD IS FUTILE

347. Plaintiff has not made a demand on the Board to institute this action against Defendants because, for the reasons detailed above and as further set forth below, any such demand would be a futile and useless act.

348. As alleged above, at each point in time from at least October 7, 2022 (the date of filing of the first derivative complaint alleging demand futility) through and including today, a majority of the members of the Board have faced a substantial likelihood of liability for failing to make any good faith effort to implement and oversee a board-level system to monitor and report on product safety, quality, and compliance issues at Abbott, for consciously disregarding red flags relating to the Company's regulatory compliance and infant formula safety, and for causing the Company to file materially false and misleading SEC filings.

349. As of today, eight of the Board's twelve members (Ford, Alpern, Blount, Kumbier, McDew, McKinstry, Starks, and Stratton) had served for over a year at the time that the Abbott Formula Recall and Sturgis Shutdown were announced in February 2022, and continued to serve

through 2022. During that time, those Defendants failed to implement controls sufficient to meet the Board's oversight responsibility with respect to product safety, quality, compliance, and regulatory issues at Abbott, and consciously disregarded red flags relating to the Company's regulatory compliance and infant formula safety, and caused the Company to file materially false and misleading SEC filings. Those eight Directors therefore face a substantial likelihood of liability for breaching their fiduciary duties.

350. As of today, seven of the Board's twelve members (Alpern, Blount, Ford, Kumbier, McKinstry, Starks, and Stratton) have served since January 2019, when safety and sanitation issues were first raised with respect to the Sturgis Facility. During that time, those Director Defendants failed to implement controls sufficient to meet the Board's oversight responsibility with respect to product safety, quality, compliance, and regulatory issues at Abbott, and consciously disregarded red flags relating to the Company's regulatory compliance and infant formula safety, and caused the Company to file materially false and misleading SEC filings. Those seven Directors therefore face a substantial likelihood of liability for breaching their fiduciary duties.

351. As of today, six of the Board's twelve members (Alpern, Babineaux-Fontenot, Blount, McDew, Roman, and Starks) serve on the Public Policy Committee of the Board, which has failed to implement controls sufficient to meet the Board's oversight responsibility with respect to quality, compliance, and regulatory issues at Abbott. Those six Directors therefore face a substantial likelihood of liability for breaching their fiduciary duties.

352. Accordingly, demand is excused.

X. CLAIMS FOR RELIEF

COUNT I
Breach of Fiduciary Duty
(Against the Director Defendants)

353. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein.

354. The Director Defendants owed and owe fiduciary duties to Abbott and its shareholders. By reason of their fiduciary relationships, the Director Defendants specifically owed and owe Abbott the highest obligation of good faith, fair dealing, loyalty, and due care in the administration and management of the affairs of the Company, including, without limitation, implementing and overseeing a system to monitor infant formula safety, the corporation's operational viability, and legal compliance. The Director Defendants had a fundamental duty to make good faith efforts to ensure that the Company's infant formula is not a public health hazard or safety risk to infants.

355. The Director Defendants consciously breached their fiduciary duties and/or acted with gross negligence in at least the following ways:

a. Consciously and repeatedly failing to implement and actively monitor or oversee a compliance and safety program;

b. Consciously disregarding their duty to investigate red flags and to remedy any misconduct uncovered; and

c. Covering up the safety risks of Abbott's infant formula.

356. The Director Defendants, individually and in concert, engaged in the above referenced conduct in intentional, reckless, or grossly negligent breaches of the fiduciary duties they owed to Abbott to protect its rights and interests.

357. In breach of their fiduciary duties owed to Abbott, the Director Defendants willfully participated in misrepresentations related to the Company's compliance with regulations designed to ensure the production of safe infant formula, failed to correct the Company's public statements, failed to fully inform themselves prior to making decisions as directors and officers, and issued misleading proxy statements with the SEC, rendering them personally liable to the Company for breaching their fiduciary duties.

358. The Director Defendants' actions as detailed in this Complaint were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

359. As a direct and proximate result of the Director Defendants' conscious failure to perform their fiduciary duties, Abbott has sustained significant damages both financially and to its corporate image and goodwill. Such damages to Abbott caused by the Director Defendants' misconduct include, and will include, operational cost increases, penalties, fines, damages awards, settlements, expenses, increased regulatory scrutiny, increased cost of capital, and other liabilities described therein.

360. As a result of the conscious and bad faith misconduct alleged herein, the Director Defendants are liable to the company.

COUNT II
Breach of Fiduciary Duty
(Against the Officer Defendants)

361. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein.

362. The Officer Defendants owed Abbott and its shareholders the highest obligations of due care and loyalty in the administration of the affairs of the Company, including, without limitation, operating the Company in compliance with laws and without undue risk to public

safety, implementing and overseeing programs to comply with laws and regulations governing the manufacture, sale, and distribution of infant formula, and reporting significant risks to the Board, regulators, and shareholders.

363. The Officer Defendants consciously breached their fiduciary duties and/or acted with gross negligence in at least the following ways:

a. Consciously and repeatedly failing to implement and actively monitor or oversee a compliance and safety program;

b. Consciously disregarding their duty to investigate red flags and to remedy any misconduct uncovered; and

c. Covering up the safety risks of Abbott's infant formula.

364. Ford, as the CEO and President of Abbott since March 2020, and as Chairman of the Board since December 2021, is responsible for Abbott's failure to: (i) implement Board-level safety reporting systems during his tenure; (ii) maintain the Sturgis Facility in a sanitary manner; and (iii) ensure the quality and safety of its infant formula product.

365. Calamari, as Senior Vice President of U.S. Nutrition, is responsible for Abbott's failure to: (i) implement Board-level safety reporting systems during his tenure; (ii) maintain the Sturgis Facility in a sanitary manner; and (iii) ensure the quality and safety of its infant formula product. He is also responsible for providing misleading testimony before the House Committee in May 2022.

366. Funck, as Abbott's Executive Vice President, Finance and Chief Financial Officer since 2020, is responsible for the issuance of misleading proxy statements and Abbott's failure to implement Board-level safety reporting systems during his tenure.

367. House, as Senior Vice President, Quality Assurance, Regulatory and Engineering Services, is responsible for the Abbott's failure to: (i) implement Board-level safety reporting systems during his tenure; (ii) maintain the Sturgis Facility in a sanitary manner; and (iii) ensure the quality and safety of its infant formula product.

368. Manning, as Executive Vice President, Nutritional Products, is responsible for Abbott's failure to: (i) implement Board-level safety reporting systems during his tenure; (ii) maintain the Sturgis Facility in a sanitary manner; and (iii) ensure the quality and safety of its infant formula product.

369. Randall, as Abbott Nutrition's Division Vice-President of Quality Assurance, is responsible for Abbott's failure to: (i) implement Board-level safety reporting systems during her tenure; (ii) maintain the Sturgis Facility in a sanitary manner; and (iii) ensure the quality and safety of its infant formula product. She is also named as a Defendant in the Consent Decree.

370. Salvadori, as Abbott's Executive Vice President and Group President, Established Pharmaceuticals and Nutritional Products, is for responsible Abbott's failure to: (i) implement Board-level safety reporting systems during his tenure; (ii) maintain the Sturgis Facility in a sanitary manner; and (iii) ensure the quality and safety of its infant formula product.

371. The Officer Defendants' actions as detailed in this Complaint were not a good-faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

372. As a direct and proximate result of the Officer Defendants' conscious and/or grossly negligent failure to perform their fiduciary duties, Abbott has sustained significant damages both financially and to its corporate image and goodwill. Such damages to Abbott caused by the Officer Defendants' misconduct include, and will include, operational cost

increases, penalties, fines, damages awards, settlements, expenses, increased regulatory scrutiny, increased cost of capital, and other liabilities described herein.

373. As a result of the misconduct alleged herein, the Officer Defendants are liable to the Company.

COUNT III
Violations of § 14(a) of the Exchange Act, and Rule 14a-9, 17 C.F.R. § 240.14a-9
(Against the Director Defendants)

374. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein, except to the extent those allegations plead knowing or reckless conduct by the Director Defendants. This claim is based solely on negligence. Plaintiff specifically disclaims any allegations of fraud with regard to this claim.

375. SEC Rule 14a-9 (17 C.F.R. § 240.14a-9), promulgated under Section 14(a) of the Exchange Act, provides:

> No solicitation subject to this regulation shall be made by means of any proxy statement form of proxy, notice of meeting or other communication, written or oral, containing any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading or necessary to correct any statement in any earlier communication with respect to the solicitation of a proxy for the same meeting or subject matter which has become false or misleading.

376. The Director Defendants negligently issued, caused to be issued, and participated in the issuance of materially misleading written statements to shareholders that were contained in the 2020, 2021, and 2022 Proxy Statements. The 2020, 2021, and 2022 Proxy Statements contained proposals to Abbott's shareholders urging them to elect and re-elect individuals to become members of the Board, approve executive compensation, and vote against stockholder proposals for the Company to adopt a policy to require an independent Chairman. The Proxy Statements, however, misstated or failed to disclose (i) Abbott's failure to establish a proper

information-reporting system relating to safety; (ii) Abbott's failure to properly respond to numerous red flags about unsafe conditions at the Sturgis Facility; (iii) Abbott's inadequate controls to safely manufacture powdered infant formula; (iv) Abbott's efforts to conceal evidence of contamination at the Sturgis Facility; and (v) Abbott's exposure to serious and significant regulatory and legal risks. By reasons of the conduct alleged in this Complaint, the Director Defendants violated Section 14(a) of the Exchange Act and SEC Rule 14a-9. As a direct and proximate result of the Director Defendants' wrongful conduct, Abbott misled or deceived its shareholders by making misleading statements that were an essential link in shareholders heeding Abbott's recommendation to elect and re-elect individuals to the Board, approve executive compensation, and vote against stockholder proposals for the Company to adopt a policy to require an independent Chairman.

377. The misleading information contained in the 2020, 2021, and 2022 Proxy Statements was material to Abbott's shareholders in determining whether or not to elect and re-elect individuals to the Board, approve executive compensation, and vote against stockholder proposals for the Company to adopt a policy to require an independent Chairman. This information was also material to the integrity of the directors that were proposed for election to the Board. The proxy solicitation process in connection with the Proxy Statements was an essential link in in stockholders heeding Abbott's recommendation to re-elect the current Board, approve certain executive compensation, and vote against stockholder proposals for the Company to adopt a policy to require an independent Chairman.

378. Plaintiff, on behalf of Abbott, thereby seeks relief for damages inflicted upon the Company based on the misleading 2020, 2021, and 2022 Proxy Statements in connection with the improper election and re-election of individuals to become members of the Board, approval of

executive compensation, and vote against stockholder proposals for the Company to adopt a policy to require an independent Chairman.

379. This action was timely commenced within three years of the date of each Proxy Statement and within one year from the time Plaintiff discovered or reasonably could have discovered the facts on which this claim is based.

X. PRAYER FOR RELIEF

380. **WHEREFORE**, Plaintiff demands judgment as follows:

a. determining that this action is a proper derivative action maintainable under the law and that demand was excused;

b. finding that Defendants consciously breached their fiduciary duties through their bad faith misconduct, including their failure to make a good faith effort to implement and oversee an effective safety monitoring and compliance system, and their conscious disregard of red flags alerting them to the corporate trauma at Sturgis and the safety of Abbott's infant formula product;

c. finding that the Officer Defendants acted with, at a minimum, gross negligence;

d. against all Defendants and in favor of the Company for the amount of any and all damages sustained by Abbott as a result of Defendants' breaches of fiduciary duties, including any and all damages compensable by statute and/or law;

e. directing the Director Defendants to take necessary actions to enhance the Company's governance to comply with applicable laws and to protect Abbott and its stockholders from repeating the harms described herein;

f. canceling the votes to re-elect the Director Defendants in connection with the annual shareholder meetings in 2020, 2021, and 2022, and ordering Defendants to disgorge

to the Company all compensation they received for service on the Board following those invalid elections;

g. awarding to Abbott restitution from all Defendants, and each of them, and ordering disgorgement of all profits, benefits, and other compensation obtained by Defendants, including payment of unvested equity-based compensation;

h. awarding to Plaintiff the costs and disbursements of the action, including reasonable attorneys' fees, accountants', consultants' and experts' fees, costs, and expenses; and

i. granting such further relief as the Court deems just and proper.

XI. JURY DEMAND

381. Plaintiff demands a trial by jury on all issues so triable.

Dated: June 27, 2023

Respectfully submitted,

/s/ Nicholas Diamand

Steven E. Fineman
Nicholas Diamand (*pro hac vice)*
Sharon M. Lee
Sean A. Petterson
Danna Z. Elmasry
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
250 Hudson Street, 8th Floor
New York, NY 10013-1413
Telephone: (212) 355-9500
Facsimile: (212) 355-9592
sfineman@lchb.com
ndiamand@lchb.com
slee@lchb.com
spetterson@lchb.com
delmasry@lchb.com

Katherine Lubin Benson (*pro hac vice)*
LIEFF CABRASER HEIMANN & BERNSTEIN, LLP
275 Battery Street, 29th Floor
San Francisco, CA 94111-3339
Telephone: (415) 956-1000
Facsimile: (415) 956-1008
kbenson@lchb.com

Joel Flaxman
ARDC No. 6292818
LAW OFFICES OF KENNETH N. FLAXMAN P.C.
200 S Michigan Ave., Suite 201
Chicago, IL 60604
Phone: (312) 427-3200
jaf@kenlaw.com

Counsel for the New York State Common Retirement Fund

2802606.15

VERIFICATION

I, Nelson R. Sheingold, being duly sworn, do hereby declare as follows:

I am Counsel to Thomas P. DiNapoli, Comptroller of the State of New York, Administrative Head of the New York State and Local Retirement System, and Trustee of the New York State Common Retirement Fund (hereinafter "NYSCRF"), and am authorized to act on his behalf. NYSCRF is a shareholder of Abbott Laboratories and has been since at least March 31, 2018. NYSCRF has retained competent counsel and is ready, willing and able to pursue this action vigorously on behalf of the Company. I have reviewed the Shareholder Derivative Complaint ("Complaint"). Based upon discussions with and reliance upon counsel, and as to those facts of which I have personal knowledge, the Complaint is true and correct to the best of my knowledge, information, and belief.

I declare under penalty of perjury that the foregoing is true and correct.

Signed and Accepted:

Dated: June 27, 2023

Nelson R. Sheingold, Counsel to the Comptroller of the State of New York, as Administrative Head of the New York State and Local Retirement System, and as Trustee of the New York State Common Retirement Fund